ARS □ CSREES □ ERS □ NASS

Manual

Title: Peer Review of ARS Research Project Plans

Number: 500-1

Date: November 22, 2000

Originating Office: Office of Scientific Quality Review, Office of the

Administrator, ARS

This Replaces: Not Applicable

Distribution: All ARS Management Units and Headquarters

This Manual describes the process employed by the Agricultural Research Service (ARS) to obtain independent and credible scientific peer review of research project plans developed to meet the objectives and aims of its National Programs. This interim Manual will be in effect for one year, during which time it will be further evaluated and modified as necessary.

The ARS Pledge to Customer Service

To practice the highest standards of integrity and ethical conduct

To dedicate ourselves to quality and excellence

To provide objective and factual information to our customers

To value and treat each customer courteously

To listen to our customers and strive to understand their needs

To appreciate the diversity of our customers and respect their contributions

To provide timely, complete, and understandable responses to customer requests

To treat our coworkers as customers

Agricultural Research Service, USDA Office of Scientific Quality Review Peer Review Program Coordinator 5601 Sunnyside Avenue; Mail Stop 5142 Beltsville, MD 20705-5142

Phone: 301-504-3282 Fax: 301-504-1251

E-mail: OSQR@ars.usda.gov

Website: www//OSQR.ars.usda.gov

1. Introduction	
The Agricultural Research Service	5
The ARS Research Programs and Research Activities	
Animal Production, Product Value, and Safety (NP 100 Series)	
Natural Resources and Sustainable Agricultural Systems (NP 200 Series)	
Crop Production, Product Value, and Safety (NP 300 Series)	
1999 Revision of ARS Peer Review Process	8
2. The ARS Peer Review Process for Research Project Plans:	The Big
Picture	
Key Characteristics of the New Peer Review Process	10
Organizational Objectives of Peer Review	
Credibility, Reliability, and Effectiveness of the Peer Review Process	12
Criteria to Ensure Quality of Peer Reviews	13
Expected Benefits of Peer Review	
Federal Laws that Impact the Review Process	14
The Administrative Procedures Act	14
The Freedom of Information Act (FOIA)	
The Federal Advisory Committee Act (FACA)	
Title 44-Public Printing and Documents	15
3. The Peer Review Process: The Details	
Sequence of Events	
Preliminary Planning	
Determination of Project Plans to be Reviewed	
Prospectus	
Project Plan	
Peer Review Panel Meeting	
Ad Hoc Peer Reviews	
Peer Reviewers	
Eligibility and Responsibilities of Peer Reviewers	
Panel Disciplines and Membership	
Conflict of Interest Guidelines	
Confidentiality of Information	
Anonymity of Reviewers	
Review Criteria	
Action Classes	
Peer Review Recommendations	

4. Summary of Responsibilities

Office of the Administrator	29
Area Directors	29
Associate Deputy Administrators and National Program Teams	29
Research Leaders, Lead Scientists, and Research Teams	
Office of Scientific Quality Review (OSQR)	
5. Glossary	22
TERMS	
ACRONYMS & ABBREVIATIONS	35
6. Exhibits Exhibit 1: Improving Research Through Peer Review; Roles of Peer Review Exhibit 2: Review and Evaluation of National Programs	39
Exhibit 3: Sample Peer Review Form	
Exhibit 4: Sample Peer Review Recommendations and ARS Response	
Exhibit 5: Contents of the Panel Chair's Statement	
Exhibit 6: Action Class Matrix	49
Exhibit 7: Sample Action Class Rating Worksheet	53
Exhibit 8: The ARS Research Project Plan Instructions and Format	
Exhibit 9: Peer Reviewer Guidelines	
EXAMPLE OF A WELL WRITTEN SET OF RECOMMENDATIONS:	
Exhibit 10: The Panel Peer Review Process: Step by Step Guidelines	66

1. Introduction

The Agricultural Research Service

ARS is the U.S. scientific research agency responsible for solving agricultural problems of national importance.

ARS research develops solutions to a wide range of problems related to food and agriculture—problems requiring long-term commitment of resources and problems unlikely to have solutions with the quick commercial benefits that would convince private industry to do the research. These problems range from protecting crops and livestock from costly pests and diseases to improving quality and safety of agricultural commodities and products, determining the best nutrition for humans from infancy to old age, sustaining natural resources, and ensuring profitability for producers and processors while keeping costs down for consumers. In addition to serving this broad range of customers, ARS provides research to support Federal action and regulatory agencies.

The Agency's researchers work at about 100 locations nationwide and a few key sites overseas. ARS employs about 7,000 people; 2,000 of them are scientists.

In addition to carrying out its research, ARS transfers the resulting technology to intermediate and end users and otherwise communicates the information gained through its research. This technology transfer and information dissemination is carried out by all ARS employees with the help and guidance of the National Agricultural Library, the Office of Technology Transfer, and the Information Staff.

The ARS Research Programs and Research Activities

The ARS is the principal in-house research agency of the U.S. Department of Agriculture (USDA). It is one of four agencies of the Research, Education, and Economics (REE) mission area. ARS is charged with extending the nation's scientific knowledge and providing science-based solutions to problems across a broad range of program areas in animal and plant health and production systems and natural resource systems.

The ARS conducts mission-driven, intramural basic and applied research to solve priority agricultural and human nutrition problems. Also, ARS conducts mission-related research authorized by Congress in the Research Title of the United States Farm Bill. ARS works collaboratively with industry, the public, and academic stakeholders and customers to develop research objectives to meet national research needs while addressing mission requirements and congressional directions.

The ARS Administrator ensures that needed National Program Action Plans are updated at least every five years and implemented (*Agricultural Research Service's Strategic Plan*, USDA; April 1999). National Program Action Plans are developed through workshops and are published for public comment and information. The workshops result in Action Plans

based on input from customers and stakeholders and provide a framework and sound foundation for:

- Coordinating and integrating research across ARS National Programs and Areas to ensure effective teamwork and to minimize duplication.
- Coordinating ARS National Programs with progress of other research institutions, such as State agricultural experiment stations and industry, to ensure that efforts are efficient and complementary.
- Ensuring that problems are addressed by the most appropriate means in terms of key scientific disciplines, teamwork, and technical approach.
- Reviewing and evaluating progress towards achievement of the objectives.
- Each ARS research project is coded to one National Program to document that more than 50% of its activities are done to help solve problems in that National Program. The 22 National Programs are distributed among three groups:

Animal Production, Product Value, and Safety (NP 100 Series)

ARS seeks to enhance the production, value, and safety of foods and other products derived from animals which have a major impact on the American economy, world markets, and the U.S. balance of trade. The ARS scientific Program in Animal Production, Product Value, and Safety conducts multi-disciplinary research to solve problems of high national priority that threaten the security, safety, and productivity of U.S. agriculture and those arising from the interaction between animal and crop production and sustainable agricultural systems. In the area of human nutrition, foods from animals are a major contributor of energy and vital nutrients in the diets of Americans. ARS collaborates with public, private, academic, and foreign research entities to increase animal production and improve product quality and safety. Through these efforts, the United States can preserve its preeminent role as food provider to the world and overcome artificial trade barriers in world markets. The 100 series National Programs are:

- 101 Food Animal Production
- 103 Animal Health
- 104 Arthropod Pests of Animals & Humans
- 105 Animal Well-Being & Stress Control System
- 106 Aquaculture
- 107 Human Nutrition
- 108 Food Safety

Natural Resources and Sustainable Agricultural Systems (NP 200 Series)

ARS seeks to enhance the quality of the environment through better understanding of, and building on, agriculture's complex links with soil, water, air, and biotic resources. The scientific Program in Natural Resources and Sustainable Agricultural Systems conducts multi-disciplinary research to solve problems arising from interactions between agriculture and the environment. New practices and technologies will be developed to conserve the Nation's natural resource base and balance production efficiency and environmental quality. ARS collaborates with foreign research entities to address global environmental quality problems. The 200 series National Programs are:

Water Quality & Management
Soil Resource Management
Air Quality
Global Change
Rangeland, Pasture and Forages
Manure and Byproduct Utilization

Crop Production, Product Value, and Safety (NP 300 Series)

Integrated Farming Systems

ARS seeks to enhance the production, value, and safety of foods and other products derived from plants which have a major impact on the American economy, world markets, and the U.S. balance of trade. The ARS scientific Program in Crop Production, Product Value, and Safety consists of multi-disciplinary research to solve problems of high national priority that threaten the security, safety, and productivity of U.S. agriculture. In the area of human nutrition, foods from plants are a major contributor of vital nutrients and fiber in the diets of Americans. ARS collaborates with public, private, academic, and foreign research entities to increase crop production and improve product quality and safety. The 300 series National Programs are:

- Plant, Microbial, & Insect Genetic Resources, Genomics & Genetic Improvement
- 302 Plant Biological & Molecular Processes
- 303 Plant Diseases

207

- 304 Crop Protection & Quarantine
- 305 Crop Production
- 306 New Uses, Quality, & Marketability of Plant & Animal Products
- 307 Bioenergy & Energy Alternatives
- 308 Methyl Bromide Alternatives

1999 Revision of ARS Peer Review Process

The Peer Review Process is the process by which a research project plan is assessed by independent expert reviewers for scientific and technical quality and for suitability of approach to achieve stated National Programs objectives. Prior to 1999, peer review was conducted by having each plan evaluated by three or more expert ARS or non-ARS ad hoc reviewers. Since this process was administered at the Area Office level as projects were initiated or renewed, reviews of project plans were not uniform in procedures or quality and were not coordinated by scientific discipline across the Agency. (See Exhibit 1: Improving Research Through Peer Review.)

The Research Title of the 1998 Farm Bill, PL105-185, set forth new requirements for peer review of ARS research projects: 1) panel peer reviews of each research project were mandated at least once every five years and 2) the majority of peer reviewers must be external (non-ARS) scientists. In September 1998, ARS commissioned a team to update the peer review process in accordance with these requirements. This team, led by an Associate Deputy Director Administrator, investigated peer review policies and procedures at other government agencies and reviewed prior ARS and REE analyses of peer review practices to identify and prioritize the modifications needed. ARS Area Directors, National Program Leaders, and Deputy Administrator and Associate Deputy Administrators of the National Program Staff also made key contributions to the revision. The new Peer Review Process was implemented in October 1999.

Office of Scientific Quality Review

The Office of Scientific Quality Review (OSQR) is an organizational unit of the Agricultural Research Service (ARS) reporting to the Associate Administrator with primary responsibility for planning and facilitating high quality scientific and technical peer review of all Agency prospective research project plans. The OSQR is a team-based organization consisting of a rotating Scientific Quality Review Officer, a full-time Peer Review Program Coordinator, and two full-time Program Assistants.

The OSQR team manages and implements the ARS peer review process, including peer review policies, processes, and procedures. The OSQR team centrally plans and conducts consolidated peer panel review sessions for each ARS National Program on a five-year cycle, with about five National Programs being reviewed each year.

The OSQR establishes the master schedule of both National Program and other review sessions, and obtains external scientists to serve as panel chairs for each panel. The OSQR team is responsible for and coordinates:

- Panel organization and composition ad hoc reviewer selection and retention
- Panel membership, retention, and contracts for services
- Reviewer instruction and panel orientation
- The distribution of review results in ARS

- Notification to panelists of the Agency response to review recommendations
- Special, ad-hoc, or re-reviews of project plans

ARS Review Systems

The Office of Scientific Quality Review is one of four review systems that evaluate ARS's operations:

- 1. The Research Position Evaluation System is a process used to classify research positions and assign an individual with the appropriate grade level. The accomplishments of individual scientists are assessed for scientific impact and quality by a convened peer panel.
- 2. Prospective review of research project plans by the OSQR employs peer evaluation to ensure technical and scientific quality of research plans.
- 3. Location, laboratory, and research unit reviews are performed periodically to assess programmatic relevance and laboratory productivity and to ensure that sound management practices and procedures are being followed.
- 4. The 22 National Programs, to which all ARS research is directed, are evaluated every five years by workshops composed of ARS personnel and National Program customers. (See Exhibit 2: Review and Evaluation of National Programs, also.)

2. The ARS Peer Review Process for Research Project Plans: The Big Picture

Key Characteristics of the New Peer Review Process

Projects are developed and reviewed for quality and programmatic relevance within the context of National Program Action Plans.

All intramural research projects are designed to address the research needs and objectives identified in a National Program Action Plan. Lead scientists and project teams are required to develop a research project plan describing the objectives, approaches, and research environment of the project. The project plans are reviewed for technical quality and programmatic relevance to a specific National Program by a panel of scientific peers.

Standards for project quality must be satisfied prior to project implementation.

Area Directors and the National Program Staff must review all results of project reviews. Area Directors and the National Program Staff will then determine the nature and extent of revisions required for each project before its approval and implementation. Panel or ad hoc peer review recommendations will not result in a redirection of Agency funds from or to an ARS research activity. However, allocated discretionary funding for a specific research project plan may be suspended until the research project plan has been determined by Area Directors and/or the Deputy Administrator of the National Program Staff to meet quality requirements.

Office of Scientific Quality Review (OSQR) centrally coordinates all peer reviews.

One office, the OSQR, is responsible for coordinating the Peer Review Process to ensure that ARS consistently and effectively implements policies made by the ARS Administrative Council and Administrator.

Panels of scientific experts are convened.

ARS convenes one or more panels of expert reviewers to discuss their individual evaluations and recommendations for project plans within a National Program. Panels are selected and facilitated by a panel chair designated for projects within a National Program. In accordance with government travel regulations and procedures, OSQR reimburses the travel and lodging expenses for all panel reviewers and panel chairs. Non-federal panel chairs are paid the current hourly salary equivalent to a GS-15-01 federal salary and non-federal panel peer reviewers are paid a stipend.

Peer review criteria are stringent.

ARS re-examined the criteria used to assess the quality and scientific merit of research plans and strengthened those criteria while promoting creative thinking and expression of fresh approaches to research. The new review criteria used by peer reviewers include programmatic relevance to National Program objectives and more relevant guidelines for assessing adequacy of approach and probability of success in accomplishing research objectives. (See Exhibit 3: Sample Peer Review Form.)

ARS now uses peer review results more efficiently throughout the Agency to improve project plans.

The results of each peer review of project plans are recorded as a matter of Agency record in the Office of Scientific Quality Review (OSQR), and the panel recommendations are distributed to the appropriate lead scientist, Research Leader, Area Director, and National Program Leader. The lead scientist responds to the review recommendations and suggestions for improvement, updates the project plan as appropriate, and provides a response and final project plan to the Area Director and National Program Leader for approval. The OSQR then provides the panel chair and reviewers with the researcher's response and notification of actions taken in response to the review. In cases of major revision, re-review (preferably by the original primary and secondary reviewers) may be required. If a project plan is considered "not feasible," the Area Director and National Program Leader will determine and document the action to be taken.

The Peer Review Process is measurable and consistent.

ARS developed standards for panel peer review procedures and action classes by which to measure the quality of research project plans. All panel peer reviews employ the same process and review criteria, and review results are assessed and addressed in a consistent manner. All intramural research projects must be reviewed and are subject to meeting quality requirements prior to implementation.

Project plan format and requirements have been updated

ARS re-examined and modified the requirements and format for research project plans (formerly referred to as project statements). The new project plan guidelines more clearly address the peer review criteria and organize information in a manner that facilitates review.

Organizational Objectives of Peer Review

The intent of ARS in seeking peer review of its research project plans is to obtain constructive, independent, and expert feedback and advice on ways to improve the scientific and technical merit and quality of each project plan. ARS must also demonstrate compliance with the legislative mandate of PL 105-185, which requires panel peer review of research projects at least once every five years.

ARS uses peer review of research project plans to ensure scientific relevance to established mission and program objectives and technical merit in terms of scientific method. Prospective peer review affords ARS scientists the opportunity to make improvements to the project design and technical approach prior to implementing the research project. Peer review helps to ensure that ARS conducts the highest quality research in support of Agency mission and program objectives.

ARS views scientific peer review as an integral part of the Agency's overall scientific program. Sound and credible scientific peer review by expert and independent scientists serves to improve the quality of research ideas, creative thinking, and alternative approaches that may not have been considered by Agency scientists and staff.

The objectives and criteria for reviewing projects funded in an intramural research environment differ from those of extramural research proposal reviews in that the research agenda is established and prescribed to the scientist according to legislative direction and mission charges. Congress sets the ARS research agenda, upon which ARS designs research initiatives based on input from customers and stakeholders. The National Program Staff establishes specific charges for research activities, outlining the nature of the research to be performed and the operating and other resources available for the project and staff. Peer reviews of funded research project plans will not be used as a formal means of obtaining advice or guidance on mission or programmatic direction, Agency management and policy matters, or the societal or economic benefits of the research. ARS research activities are appropriated by Congress and often mandate specific amounts of funding for specific or directed research at designated locations within the United States or abroad. As a result, ARS is often limited in its capacity to supplement or redistribute funding and resource levels among Congressional districts, laboratories, agricultural commodities, and research initiatives.

Credibility, Reliability, and Effectiveness of the Peer Review Process

ARS considers the credibility, reliability, and effectiveness of its Peer Review Process to be critically important and has put several measures in place to ensure the integrity and quality of the Peer Review Process.

Objectivity and independence of peer reviewers is vital to the credibility of the Peer Review Process. Public Law 105-185 established that the majority of panel reviewers be external to ARS. ARS has added factors for determining whether a potential reviewer, internal or external, possesses a real or potential conflict of interest and therefore would be prohibited from serving as a panel or ad hoc reviewer for a specific research project plan. (See section on "Conflict of Interest Guidelines.") ARS interprets objectivity to also mean that the reviewer is reasonably free from institutional or personal bias regarding the research program or the research project(s) being reviewed. Independence from the research activity being reviewed means that the reviewer must not be directly involved in

the work being planned or performed or involved with any members of the subject research team in another capacity.

Another measure ARS has taken to ensure the credibility of the Peer Review Process has been to place responsibility for panel member selection primarily on external and independent panel chairs. ARS scientists, managers, and National Program Staff may recommend panelists, but the panel chair is under no obligation to use the recommendations. ARS reserves the right to allow the SQR Officer to approve panel membership for the purpose of eliminating a conflict of interest or in fulfilling the Agency's obligation to create panels with a diverse membership (Departmental Regulation 1041-2, Diversity in Task Force and Committee Assignments.)

Panel results should be reliable in that a comparable panel of objective experts would be likely to produce the same or a very similar recommendation for a particular project plan. ARS requires the consistent application of policy and procedure in conducting all panel peer review sessions to reduce operational variability. All ARS peer review panels should operate according to prescribed policies and rules for conducting peer reviews. The effectiveness of the Peer Review Process ultimately depends on the prudent manner in which ARS heeds and incorporates reviewer suggestions into research plans.

Criteria to Ensure Quality of Peer Reviews

Credible and effective peer review of ARS research project plans ultimately rests on having the appropriate scientific peers thoroughly review research plans in an objective and constructive manner according to the criteria established for assessing scientific quality and merit. (See Exhibit 3: Sample Peer Review Form.)

Several factors are required for high quality peer reviews:

- Clear and explicit peer review objectives
- Appropriate panel membership in terms of the right number and mix of scientific disciplines and backgrounds necessary to adequately and thoroughly assess the research project plans. (Expertise not represented on the panel can be obtained by ad hoc review of certain project plans.)
- The independence and objectivity of the peer reviewers and the absence of real or potential conflicts of interest
- Appropriate criteria for assessing technical and scientific quality and relevance to programmatic objectives
- Adequate time for reviewer preparation prior to the panel meeting
- Adherence to procedures regarding reviewer anonymity and the confidentiality of research project plan information

Expected Benefits of Peer Review

As the ARS Peer Review Process serves primarily to obtain expert, independent review of the scientific and technical quality of Agency research project plans, the primary customer of the Peer Review Process is the lead scientist and research team that developed the project plan.

The primary benefit of the Peer Review Process is the enhanced scientific and technical quality of our research and the validation of its merit. ARS scientists have the benefit of objective and expert review in developing the research approaches and designing experiments.

The new Peer Review Process places an increased emphasis and importance on up-front and thoughtful planning and design of research projects. Even if intermediate research results require the scientific team to reformulate their research project design and approach, the benefits of early thoughtful consideration to the objectives and methods of the research serves to improve the quality of the work performed.

The following can be considered secondary benefits of the Peer Review Process that serve to enhance the overall planning, coordination, and communication skills of the ARS scientific workforce:

- An increased awareness of the relationships and multi-disciplinary linkages among research activities within a National Program
- Increased communications and collaboration among National Program Teams and the research scientists planning and performing the research
- An increased emphasis on clearly communicated objectives and approaches in research project plans
- An increased knowledge and appreciation of ARS research activities and capabilities by non-ARS scientists.

Federal Laws that Impact the Review Process

The Administrative Procedures Act

Public comment solicited from the general public through the *Federal Register* or other means is often required prior to making significant decisions or actions that lead to significant decisions according to provisions of the Administrative Procedures Act. Public comment is open to all issues, whereas peer review is limited to the consideration of technical issues. Thus, peer review recommendations are written by a small group of independent subject-matter experts and are not open to public involvement.

The Freedom of Information Act (FOIA)

External groups may obtain general, non-sensitive peer review data via a request made in compliance with the ARS Freedom of Information Act procedures (ARS 158.1 FOIA & Privacy Act Procedures; February 23, 1998). These procedures outline the limitations on the release of certain types of information, such as the names and addresses of peer reviewers and the right for the OSQR to delegate access to individual research project plans to the Area Directors.

The Federal Advisory Committee Act (FACA)

FACA defines the operating requirements for formal and established federal advisory committees. Since the Peer Review Process does not require chartered peer review committees and only one reviewer determines the final recommendations, none of the provisions of FACA apply.

<u>Title 44-Public Printing and Documents</u>

Title 44 covers all recordkeeping and documentation rules for Federal agencies. Sec. 3101. "Records management by agency heads; general duties" directs all agencies to develop procedures to properly document agency decisions. The OSQR records the results of all peer reviews as a matter of Agency record. Individual peer review forms remain confidential in OSQR and are not distributed to other offices in ARS. No peer review-related documents are distributed externally; however, annual reports about the overall success of the Peer Review Process and participating peer reviewers are available upon request.

3. The Peer Review Process: The Details Sequence of Events

Preliminary Planning

The preliminary planning phase consists of 1) creating the list of projects to be peer reviewed, meaning all ARS research projects coded greater than 50% to the subject National Program, and 2) determining those projects that must be postponed or exempted. (See "Research Project Plans Reviewed" section.) Approval and coordination is required at the National Program Staff and Area levels of the ARS. OSQR reviews the rationales for postponing projects and confirms that the appropriate managers were involved in developing the list.

Concurrently, the National Program Teams (NPT) review the research assignments each project has been given related to its National Program Action Plan. The NPT often prescribes a set of objectives and approach for the research. In other cases, the NPT may merely request to review a working draft of the prospectus and provide feedback. This coordination between the research unit and the NPT is established early on via a "direction memo," transmitted with OSQR's Peer Review Process directions. The information provided includes:

- a list of steps and deadlines for the specific peer review session
- directions for the prospectus format and project plan format
- instruction to read the criteria the peer reviewers will use
- instruction to suggest peer reviewers
- contact information

Determination of Project Plans to be Reviewed

A research project's plan must be peer reviewed for quality at least once every five years, usually along with all other project plans developed for its primary National Program (the National Program to which more than 50% of a project's objectives apply). Research project plans that have been panel reviewed but are subsequently redirected or significantly altered in terms of goals and approaches must develop a new or modified research project plan and may be ad hoc peer reviewed in its entirety or only the new portion, as requested by Area Management and its associated National Program. All project plans must be included in panel reviews, unless exempt or postponed. Project plans that were ad hoc reviewed within the last two years are also included in panel reviews; however, lead scientists may submit the results of the ad hoc review to panel reviewers.

Several situations could merit an exemption or postponement of peer review (see below). However, most sanctions are made because 1) the lead scientist or other critical member of the research team is absent during the Peer Review Process or 2) the project is funded by ARS, but not necessarily led by ARS. Other situations may arise and are handled on a case-by-case basis. (See Exhibit 10: The ARS Panel Peer Review Process: Step by Step Guidelines for specific directions on how to request an exemption or postponement.)

Exempting Project Plans from a Review

A project plan may be exempt from the ad hoc or panel peer review if:

- 1. It is a new project created by combining or splitting projects that were recently panel peer reviewed as separate or single projects, respectively, and the objectives and approaches of the research have not been substantially altered.
- 2. The project has no scientific activities or staff and is part of a strategy to appropriate funds to other projects. Projects designed for similar budgeting situations--but do have some scientific activity *related* to a more comprehensive, problem-solving project--may be peer reviewed as a part of the comprehensive project plan.

Postponing Project Plans from a Review

Projects may be postponed for a peer review if:

- 1. The National Program Leader and Area Director agree that a vacancy of a critical member of the research team exists or critical team member cannot meet the writing deadlines because of a medical condition or professional endeavors (e.g., essential study leave).
- 2. The lead scientist's Area Director determines that the lead scientist has not been assigned to his/her position for sufficient time to be prepared to complete the requirements of the peer review process.
- 3. The Area Director and National Program Team agree that the project is experiencing significant reorganization to the extent that unresolved issues will prevent the lead scientist from completing the project plan in a timely manner.
- 4. The SQR Officer is a member of the project.
- 5. The Area Director and National Program Leader agree that the project was incorrectly assigned to the subject National Program. The project must then be peer reviewed in the

next ad hoc or panel peer review session scheduled for the National Program to which it has been re-assigned.

- 6. The National Program's Action Plan is incomplete. However, project plans can be ad hoc peer reviewed and demonstrate their relevance to the National Program's <u>program statement</u> if all of the following also apply:
 - a. the program statement contains current programmatic goals and descriptions of problems the projects are investigating,
 - b. the objectives of the projects are not expected to significantly change upon completion of the Action Plan, and
 - c. use of the program statement in lieu of the Action Plan is approved by the appropriate Associate Deputy Administrator.

Prospectus

A 2-page prospectus serves as an expedited communication tool between all levels of the ARS to establish each project's objectives and approaches to meet plan objectives. The prospectus is used by OSQR to identify the expertise needed in peer reviewers. Immediately after obtaining approved prospectuses, panel chairs and OSQR begin retaining reviewers. The prospectus states objectives, need for research, approach and procedures, collaborations, and conflicts of interests.

Project Plan

The project plan is the research document that describes in detail the proposed research project outlined in the prospectus. The plan must be written and approved, peer reviewed, revised, and finally implemented. The 15-page plan details the objectives; the need for research; the scientific background of the problems being addressed; the experimental plan; and the project's milestones and expected outcomes. Each plan concludes with a short statement of past accomplishments of each investigator and a statement concerning health, safety, and other issues of concern. (See Exhibit 8: ARS Research Project Plan Format.) Prior to sending project plans to peer reviewers, OSQR ensures that each plan is approved by the Laboratory/Center/Institute, National Program Team, and Area Director.

Peer Review Panel Meeting

Individual research project plans are reviewed for quality and programmatic relevance as a group, according to their common primary National Program (coded greater than 50%). This allows for thematically related projects in otherwise diverse laboratories and geographic locations to be developed, peer reviewed, and then implemented in a more collaborative and synchronized fashion. The panels are organized to review the research project plans of a National Program for a one-time peer review session and are then dissolved.

OSQR plans and conducts peer review sessions for projects in each National Program on a five-year cycle. About five National Programs, encompassing 200-250 research project plans, are the subject of peer review sessions each year. (See the Panel Peer Review Schedule on the following page.) National Programs encompassing more than 25 projects are divided into more than one panel peer review to address thematically or discipline-related projects within the Program.

National Program	Panel
Year 2001	
Animal Health (NP 103)	May 2001
Water Quality & Management (NP 201)	August 2001
Animal Well-Being & Stress Control Systems (NP 105)	December 2001
Air Quality (NP 203)	December 2001
Plant Diseases (NP 303)	December 2001
Year 2002	
Rangeland, Pasture & Forages (NP 205)	May 2002
Food Animal Production Systems (NP 101)	August 2002
Methyl Bromide Alternatives (NP 308)	August 2002
Plant Microbial/Insect Germplasm Conservation/Development (NP 301)	December 2002
Year 2003	
Crop Production (NP 305)	May 2003
Integrated Farming Systems (NP 207)	May 2003
Human Nutrition (NP 107)	August 2003
New Uses, Quality/Marketability of Plant/Animal Products (NP 306)	December 2003
Year 2004	
Arthropod Pests of Animals and Humans (NP 104)	May 2004
Bioenergy & Energy Alternatives (NP 307)	May 2004
Aquaculture (NP 106)	August 2004
Global Change (NP 204)	August 2004
Crop Protection & Quarantine (NP 304)	December 2004
Manure and Byproduct Utilization (NP 206)	December 2004
Year 2005	
Food Safety (NP 108)	August 2005
Soil Resource Management (NP 202)	December 2005
Plant Biology & Molecular Processes (NP 302)	December 2005

Panels receive an orientation from the Office of Scientific Quality and the National Program Staff. The National Program Leader or a member of their team must discuss the nature and relationships between all of the research projects coded or related to the National Program. The panelists are encouraged to review the National Program's Action Plan and National Program Overview before the meeting.

Each panelist reviews approximately 24 research project plans over a 5-week period and then convenes in Beltsville, MD to thoroughly discuss each project. While each panelist evaluates every plan, they are also assigned by the panel chair as primary reviewer of an average of three plans and secondary reviewer for three plans. (See Glossary for a definition of primary reviewer and secondary reviewer.) Panelists individually

- evaluate each project plan for scientific and technical quality based on criteria established by ARS,
- provide recommendations on how to improve each project plan, and
- assign an action class for the level of needed improvement to each project plan.

A typical panel consists of 8 peer reviewers plus one panel chair. An ad hoc reviewer may be sought if special expertise is needed for one or more of the projects. Prior to the panel session, each reviewer reads every research project plan and provides written comments. Primary and secondary reviewers provide in-depth comments, whereas other reviewers may simply make bulleted statements or identify questions in preparation for the discussions. Primary and secondary reviewers come prepared to lead the discussion of the projects they have been assigned. If an ad hoc reviewer was needed on a project, the appropriate primary reviewer presents the ad hoc reviewers comments. After each plan is discussed, each panelist documents his/her judgment about the degree of modification needed by assigning an action class (See Exhibit 6: Action Class Matrix.) on a form provided at the panel meeting. (See Exhibit 9: Peer Reviewer Guidelines also.) Panels devote approximately one hour per plan over a 3-day period.

The panel discusses the strengths and weaknesses of each project plan and contributes to the final recommendations. Review criteria, asked in their question format, guide the discussion. (See Exhibit 3: Sample Peer Review Form.) The panel recommendations include a summary of salient points made by panelists during the discussion and a rationale for their recommendations. Primary reviewers compose a review that captures salient comments of the panel, as well as recommendations to which a response should be given. This review is submitted to the panel chair for validation by the last day of the meeting. OSQR distributes the action classes and recommendations to the Area Directors.

Ad Hoc Peer Reviews

Ad hoc peer reviews are peer reviews for technical and scientific quality conducted by one or more expert and independent scientists outside a regularly scheduled panel. Ad hoc reviews for new or significantly modified projects have a similar process as a panel review process, however:

- the reviewers are not convened
- there is no panel chair
- the reviewers are not paid a stipend to perform the review
- the set of projects in the review do not include all the projects making up the National Program
- the SQR Officer compiles the recommendations for project plans rated as needing major revision or not feasible and directs the research team to respond to each recommendation. Research units receiving a no revision, minor revision, or moderate revision rating on their project plans read and consider all of the individual ad hoc peer reviews turned in.

Ad hoc reviewers receive project plans, perform in-depth reviews and mail the peer review form with an action class assignment back to the OSQR. The SQR Officer writes the recommendations for each project plan, based on the input from individual reviews. Finally, OSQR distributes the action classes and recommendations to Area Directors. Ad hoc reviewers are subject to the same confidentiality and conflict of interest policies as panel reviewers. Ad hoc reviewers fall into one of two categories:

1. Ad Hoc Reviews Outside the National Program Peer Review Panels

ARS recognizes that research projects are not static within even the best developed National Program Action Plans; they may be modified or created for reasons such as changes in mission or programmatic direction, Congressional mandates, redirection or new objectives, new initiatives or funding, and organizational and staffing changes. A new research project plan, or one that has been dramatically changed, may require an ad hoc peer review if the panel review session for its National Program begins more than two years later. Existing research projects that have been combined into a single project need not be peer reviewed again if the goals and approaches of the research have not been substantially altered in the process. (See section on "Determination of Project Plans to be Reviewed.)

Each research project plan being reviewed for quality through the ad hoc review process is required to receive at least three independent ad hoc reviews. The SQR Officer selects ad hoc reviewers from a pool of nominated reviewers. Ad hoc review recommendations are compiled by the OSQR and distributed to the appropriate Area Director. However, the SQR Officer writes the final recommendations and action class based on the ad hoc reviewers' comments and recommendations when the cumulative action class is "major revision required" or "not feasible." Lead scientists are required to formally submit their response to an ad hoc review to their Area Director.

2. Ad Hoc Reviews to Supplement Expertise on a Panel Peer Review. Panel chairs may determine it is necessary or desirable for a particular research project plan to be critically

reviewed by a scientific expert not available on their panel. In this case, the OSQR can send the research project plan to one or more ad hoc reviewers to supplement the reviews of the panel. Panel chairs select panel reviewers. An ad hoc reviewer used in conjunction with a panel may not be designated as the primary reviewer. The completed ad hoc review is given to the primary reviewer prior to the panel review session. The primary reviewer must discuss the findings and recommendations of the ad hoc review during panel discussions of the project plan for the panel's consideration.

Project Plan Revision and Project Implementation

Along with the panel's written recommendations, OSQR sends the Area Directors a worksheet that lists each reviewer's judgment of which action class each project plan should have. The action classes are also converted to a numerical equivalent, averaged, and a final action class rating is assigned to the plan by the SQR Officer. (See Exhibit 7: Sample Action Class Rating Worksheet.)

If the action class is:

- 1. No revision required. No revision is required, but minor changes to the project plan may be made.
- 2. Minor revision required. The project plan is basically feasible as written but requires some revision to increase quality to a higher level.
- 3. Moderate revision required. The project plan is basically feasible as written but requires moderate revision to one or more objectives, perhaps involving changes to the experimental approaches, in order to increase quality to a higher level. The project plan may also need some rewriting for greater clarity.
- 4. Major revision required. Substantial revision to one or more objectives is necessary, but the project plan should be sound and feasible after significant revision.

Scientists are required to submit a formal statement to their Area Director demonstrating their response to peer reviewers' recommendations. Responses are inserted after each recommendation on the peer review form. (See Exhibit 4: Sample Peer Review Recommendations and ARS Response.) The response must clearly indicate which recommendations were adopted, include other changes that were made, and cite sound rationale for not accepting recommendations, if applicable. The Area Directors subsequently submit the formal response to the SQR Officer.

Research leaders and lead scientists revise their project plans and prepare responses to each peer review recommendation for their plans. Lead scientists solicit comments and obtain approval of the revised project plans from their Laboratory, Center, or Institute Director. The revised project plan, the ARS response, and original signed coversheets are then forwarded to the Area Director. The Area Director reviews and approves each revised project plan, as well as solicits input and approval from the National Program Team. The Area forwards the fully approved revised project plan, ARS response, and original signed coversheets to OSQR. OSQR delivers the ARS response to peer reviewers.

OSQR certifies the ARS response to the peer review and that the process is complete and in the best interest of the Agency. The certification letter also contains the termination date, the next scheduled peer review, and public access to information pertaining to the review.

Note that projects requiring "major revision" may be re-reviewed (preferably by the original primary and secondary reviewers) under the advice of ARS management.

If the final action class is:

5. *Not feasible*. The project plan has major flaws or deficiencies, and cannot be simply revised to produce a sound project. If the project is not terminated, a complete redesign and rewrite are required.

The Area Director of that project is responsible for convening a team of representatives from the Area, Laboratory, Center/Institute (if applicable), and National Program Staff to determine the best course of action to respond to the peer review.

- a. If the ARS opts for a re-review, the project is revised and approved over a 10-week period, using the same steps involved in preparing a project plan prior to a peer review. (See "Project Plan Development" above). OSQR re-sends the project to the original primary and secondary reviewers. The project is peer reviewed within a 4-week period.
- b. If the ARS opts to have the project completely re-written, possibly by different scientists, the project is included in the next scheduled ad hoc peer review of projects within the National Program. The next peer review of the project occurs about a year later.
- c. ARS may opt to terminate the project.

Area Directors send OSQR a memo discussing the course of action selected and their rationale for that decision. OSQR further informs the peer reviewers of ARS's decision and makes arrangements for a re-review if requested.

Peer Reviewers

Eligibility and Responsibilities of Peer Reviewers

Peer reviewers are individual scientists and technical experts who possess relevant and extensive knowledge and experience in a field of science and can use that expertise to critically evaluate specific scientific research project plans for scientific and technical quality. Peer reviewers may be ARS or non-ARS scientists who are independent of the research being planned or performed and qualified to serve as an expert reviewer for a particular field of science or technical specialty. Generally, to be considered an expert in a field of science, a peer reviewer must be accomplished in his/her field and be nationally and/or internationally recognized as an authority in the field. Peer reviewers may be members of an academic institution, as well as Agency customers or stakeholders, provided they meet the above criteria. Peer reviewers serve as members of organized panels or as ad hoc peer reviewers.

Peer reviewers lend their expertise and experience to ARS in assessing the scientific and technical quality of research project plan approaches, methods, procedures, and use of material resources. Peer reviewers, unencumbered by internal or organizational viewpoints and associations to the research itself, are in a unique position to provide constructive feedback to ARS scientists. This feedback serves to improve the quality of ARS research by suggesting better alternatives and approaches or even stimulating creativity and new ideas about the science or methods employed. Peer reviewers serve as individual advisors to ARS. While their recommendations are not binding upon the Agency, their insights and suggestions are carefully considered to ensure the quality and credibility of the Agency's overall scientific program.

Peer reviewers are responsible for providing credible, objective, and thorough reviews of ARS research project plans according to the objectives and quality criteria set forth by the ARS. (See Appendix C1: Sample Peer Review Form.) Peer reviewers are also required to sign and honor confidentiality agreements to protect potentially sensitive information included in ARS research project plans. Peer reviewers are anonymous to the researchers responsible for each project plan and are expected to retain their anonymity as a peer reviewer in their discussions with anyone outside the OSQR.

All individuals who serve as a panel peer reviewer for ARS are reimbursed for their travel and lodging expenses according to government travel regulations and procedures. Non-federal panel chairs are paid the current hourly salary equivalent to a GS-15-01 federal salary. Non-U.S. government panel reviewers are also paid a stipend.

Panel Disciplines and Membership

Panel Chairs

A panel chair is a non-ARS scientist, designated by the Scientific Quality Review Officer to select the membership of, lead, and administer a convened peer review panel. Although panel chairs are also experts in the issues dealt with in the project plans, they do not participate in peer reviews. Panel chairs assign primary and secondary reviewers to each project and determine if ad hoc reviews are needed to supplement the expertise of the panel. (See Glossary for a definition of primary reviewer and secondary reviewer.) Panel chairs are responsible for ensuring review quality, enforcing review standards and procedures, moderating panel discussions, and collecting panel materials at the conclusion of a panel review for submission to the OSQR. When the peer review is completed, the panel chair submits a statement discussing the quality of the peer review session to the SQR Officer. (See Exhibit 5: Contents of the Panel Chair's Statement.)

Panel Selection

Panelists are selected according to the scientific disciplines necessary for a thorough and expert peer review of ARS's research project plans. Panelists are retained about six months prior to their review period and meeting to allow ample time to fill each primary and secondary reviewer slot. The majority of panel peer reviewers must be external (non-ARS) scientists. Panels are designed to provide balanced representation of a variety of backgrounds and perspectives on scientific issues relevant to the research activities represented in their assigned project plans. Attention is given to diversity parameters including gender, race, ethnic background, and disabilities, as well as seeking representatives from private sector and non-land grant colleges, universities, and research institutions/centers.

The OSQR facilitates the panel chair's peer reviewer selection process. Internal and external scientists, ARS management, and stakeholders may suggest reviewers to the Scientific Quality Review Officer but are not directly involved in the panelist selection. (See section on "Anonymity of Reviewers" below.) The SQR Officer is responsible for ensuring as much diversity in peer panels as possible (e.g., institutional, underrepresented groups, and geographic base.) while maintaining the best available expertise.

Conflict of Interest Guidelines

A peer reviewer is considered to hold a real or potential conflict of interest if he/she possesses an institutional affiliation with the research project laboratory, investigators, or collaborators or would gain some benefit from the project, financial or otherwise. Furthermore, a conflict of interest exists if the peer reviewer has had any of the following relationships with the lead scientist or other member of the research team in the past four years:

- Collaboration on research projects
- Co-authorship
- Thesis or post-doctoral advisorship
- Work as a graduate student or postdoctoral associate

Peer reviewers with a conflict of interest with regard to a particular plan will excuse themselves from all considerations of that plan. External scientists serving as a peer reviewer for a research project are not precluded from subsequently entering into agreements or collaboration with any ARS research unit or scientist.

Confidentiality of Information

ARS research project plans may include information about the underlying research and existing or anticipated research results that is considered by ARS to be proprietary or confidential. Reviewers may not copy, quote, discuss, or otherwise use material from this proposal outside the panel review process. Reviewers must leave all project plans and review materials in the possession of ARS at the conclusion of a panel meeting and erase such materials from their computers, disks, or other electronic storage techniques.

Anonymity of Reviewers

To foster reviewer openness and objectivity, ARS does not disclose the membership of a peer review panel to its scientists or staff. Panel chairs are not anonymous but are required to honor this policy as well and may not discuss review assignments other than with the OSQR. Once a panel is convened, subject members of the National Program Team will be present to provide an overview of the Program and will therefore know the identity of the panelists. The National Program Team is prohibited from disclosing panel membership to other ARS staff as well.

Should any reviewer be contacted by an ARS scientist or member of the National Program Staff concerning the review, the reviewer must not discuss the matter and is requested to contact the OSQR to handle the situation. OSQR may be reached at (301) 504-3282.

Review Criteria

Project plans are assessed for quality according to three broad criteria: merit and significance, adequacy of approach and procedures, and probability of success (see Exhibit 3: Sample Peer Review Form). The ARS sets the review criteria; however, peer reviewers are encouraged to make additional recommendations for consideration. Specific questions regarding each of the three criteria that should be addressed are discussed below.

Criterion 1: Merit and Significance

For this criterion, ARS is primarily interested in whether the problems to be solved or addressed fit within the National Program Action Plan to which the Project Plan is assigned. The National Program Action Plan has been developed with input from stakeholders, congressional mandates, customers, and ARS and non-ARS scientists. Other aspects of these criteria that should be addressed are:

- Will the successful completion of the project enhance knowledge of a scientifically important problem?
- Will the project lead to the development of new knowledge and technology?
- Are you aware of any other data/studies relevant to this research effort?
- If applied research, of what value is the research to its customers?

Criterion 2: Adequacy of Approach and Procedures

This evaluation criterion measures the scientific quality of the proposed research. Questions to be answered are:

- Are the hypotheses and/or plan of work well conceived?
- Are the experiments, analytical methods, and approaches and procedures appropriate and sufficient to accomplish the objectives?
- How could the approach or research procedures be improved?

Criterion 3: Probability of Successfully Accomplishing the Project Objectives The feasibility of the project is evaluated by this criterion. The panel will determine:

- The probability of success in light of the investigator or project team's training, research experience, preliminary data if available, and past accomplishments
- Whether the objectives are both feasible and realistic within the stated timeframe and with the resources proposed
- Whether the investigators have an adequate knowledge of the literature as it relates to the proposed research.

Satisfying all three criteria is essential to approval of a Project Plan.

Action Classes

Action classes describe the level of modification necessary to respond to peer reviewer's suggestions. Most project plans will receive some suggestions for improvement as a result of panel evaluations. Action classes provide management with a measurement of project plan quality. The five action classes are:

- 1. No revision required. No revision is required, but minor changes to the project plan may be made.
- 2. Minor revision required. The project plan is basically feasible as written but requires some revision to increase quality to a higher level.
- 3. Moderate revision required. The project plan is basically feasible as written but requires moderate revision to one or more objectives, perhaps involving changes to the experimental approaches, in order to increase quality to a higher level. The project plan may also need some rewriting for greater clarity.
- 4. Major revision required. Substantial revision to one or more objectives is necessary, but the project plan should be sound and feasible after significant revision.
- 5. Not feasible. The project plan has major flaws or deficiencies, and cannot be simply revised to produce a sound project. If the project is not terminated, a complete redesign and rewrite are required.

See Exhibit 6 for a matrix describing characteristics of projects plans assigned to the five action classes.

Peer Review Recommendations

Each reviewer is instructed to clearly identify his/her recommendations and provide a rationale for each recommendation. The intent of these peer reviews is to improve project plans. Thus, it is reasonable to expect the majority of the peer reviews to contain more recommendations than general comments and compliments. ARS must reasonably consider accepting all peer review recommendations. Recommendations that are not accepted require a justification. (See Exhibit 4: Sample Peer Review Recommendations and ARS Response.)

Panel or ad hoc peer review recommendations will not result in a redirection of Agency funds from or to an ARS research activity. However, allocated discretionary funding for a specific research project plan may be suspended until the research project plan has been determined by Area Directors and/or the Deputy Administrator of the National Program Staff to meet quality requirements.

4. Summary of Responsibilities

Office of the Administrator

Provides executive-level oversight of the ARS Peer Review Process, communicating Agency policy and procedures for peer review to internal and external parties. Stays abreast of program performance and issues and makes adjustments to the Peer Review Process as necessary. Provides annual updates on the Peer Review Process to the Research, Extension, Education, Economics Advisory Board, and Congressional committees. Represents ARS in matters related to peer review. Selects Scientific Quality Review Officer on an annual basis.

Area Directors

Monitor the progress of research project plans developed for various National Programs. Review and approve project plans for submission to the National Program Staff and the OSQR. Provide direction and instruction to ARS researchers in meeting scientific quality requirements and in addressing the recommendations and suggestions of peer reviewers. Provide input into the Peer Review Process-related policies and procedures.

Area Directors also:

- Identify and/or approve members of research teams
- Concur with National Program recommendations to add or delete projects from the group of projects being peer reviewed
- Initiate peer review approval records in the Research Management Information System and the implementation of project plans
- Review and approve project plan prospectuses
- Review and approve all project plans, as well as gain input and approval from National Program Teams.
- Manage lines of peer review-related communication involving Area laboratories
- Lead the interpretation and use of peer reviews

Associate Deputy Administrators and National Program Teams

Provide programmatic directions to lead scientists through the Area Director. National Program Teams, guided by a designated leader, give lead scientists advice on their project's objectives and approach early in the Peer Review Process, often using the project plan prospectus as a communication tool. Review research project plans to verify adherence to programmatic direction and provide input to the OSQR in determining scientific discipline requirements for panels. Provide materials and information about a National Program to OSQR for reviewer use. Provide an overview of the National Program to a review panel concerning the Program's design, influence of workshops, assignments of and relationships between projects.

National Program Teams also:

- Review and approve list of projects to be peer reviewed
- Give scientific direction to lead scientists
- Distribute directions and schedule to initiate peer review sessions

Research Leaders, Lead Scientists, and Research Teams

Develop research project plans according to programmatic direction provided by the National Program Team and according to guidelines established by the OSQR. Submit project plans to the Area Director for review within specified timeframes. Review peer review recommendations and make appropriate modifications to research project plans for submission to the Area Director and National Program Team. Submit formal responses to recommendations made by peer reviewers to OSQR.

Office of Scientific Quality Review (OSQR)

Has primary responsibility for planning and facilitating high quality scientific and technical peer review of all Agency prospective research project plans. Manages the Peer Review Process, including policies, processes, and procedures. Centrally plans and conducts consolidated panel peer review sessions for projects within each National Program and coordinates ad hoc reviews of individual projects as necessary. Reports to the Associate Administrator. The OSQR team consists of the Scientific Quality Review Officer, Peer Review Program Coordinator, and two assistants.

Scientific Quality Review Officer (SQR Officer)

Provides professional scientific oversight of the Peer Review Process and panel operations. Enforces Agency policy and requirements regarding the Peer Review Process. Oversees the transfer of peer review recommendations from peer reviewers to Area Directors, and the transfer of ARS responses to panel recommendations to peer reviewers.

Peer Review Program Coordinator

Manages the day-to-day operations of the Peer Review Process. Communicates and enforces Agency policy and requirements regarding peer review. Develops review schedules and provides initial peer review direction to National Program Leaders, Area Offices, and researchers. Makes logistical arrangements for panel peer reviews and coordinates the flow of information and materials to and from reviewers. Creates and maintains official Agency records concerning peer review throughout the life of the peer-reviewed project (plus an additional two years). Performs administrative duties to support the Peer Review Process, including processing reimbursements for reviewer expenses and external reviewer stipends.

During each peer review session, the OSQR team:

- Sets key deadlines
- Retains panel chairpersons (panel chair)
- Oversees panel chairs in the selection of panel peer reviewers
- Provides orientation to panel chairs and panels
- Assists panel chairs in retaining ad hoc peer reviewers
- Maintains the official public record of all peer review-related documents and the process of retaining panel chairs and peer reviewers
- Ensures integrity in the recommendation development and judgement process

- Reports results of peer review of individual project plans to Area Directors and National Program Staff Management
- Certifies each ARS peer review response and communicates responses back to panel
- Routinely provides peer review orientations for National Program Teams, and as requested for new scientists, lead scientists, research leaders, administrative staff, and other employees

5. Glossary

TERMS

Action Class

Action classes refer to the degree of revision peer reviewers believe project plans need. The action classes correspond to the extent of peer reviewers' recommendations and are meant to give ARS management an overall idea of the quality of project plans.

Current Research Information System (CRIS)

An electronic system for the filing and retrieval of information about individual agricultural research projects. All ARS research projects are part of the CRIS and are assigned a CRIS number.

Independent (Peer Reviewer)

A peer reviewer is said to be independent of the project plan if he or she was not involved in the plan being reviewed and has no benefit from the funding of the project. Furthermore, independent peer reviewers must have no conflicts of interest with project plans that they review. Independent peer reviewers ensure that a project plan is impartially reviewed.

Research Unit

The ARS unit performing the research that is subject to peer review. Research leaders scientifically and administratively manage ARS labs. Typically, a lab is comprised of 5-10 scientists, support staff, and several temporary student and postdoctoral employees. Most labs are associated with a specific ARS Institute or Center that also provides direction. The program and mission of the lab is often limited. Discipline or program gaps might be filled by collaboration with other labs in ARS or elsewhere.

National Program Staff (NPS)

The NPS serves the Administrator of ARS in developing and coordinating research plans and strategies on a national basis. The NPS sets National Program directions, establishes priorities, and allocates resources. Considerable interaction with Area Directors, stakeholders, and scientists is required to successfully accomplish the NPS's mission. The NPS is composed of approximately 40 research scientists plus support personnel located in Beltsville. MD.

National Program Action Plan

A document written as a result of the issues raised by Congress, stakeholders, and researchers associated with a particular National Program. The Action Plan addresses 1) Rationale and Purpose for the Program; 2) Background; 3) Program Components; 4) Anticipated Outcomes/impacts Over 5 Years; and 5) Research Objectives by Program Component.

National Program Overview

A presentation or document given to peer reviewers to discuss the components, objectives, and relationships between projects associated with a particular National Program. The National Program Overview is provided in support of the National Program's Action Plan.

Panel Chair

The facilitator and manager of a peer review panel. Panel chairs must meet the same expertise, confidentiality, and freedom of conflicts of interests requirements as peer reviewers. They are often sought as panel chairs because of their facilitation skills and supreme knowledge of other experts in their field. Panel chairs are responsible for retaining peer reviewers for their panel, becoming knowledgeable of ARS's peer review criteria and other policies, managing the peer review meetings, and validating the final peer review recommendations.

Peer Review

The process by which independent and expert reviewers assess a research project plan for scientific and technical quality and suitability of approach to achieve a stated National Program.

Peer Reviewer

An individual designated by ARS as qualified and capable of independently and critically assessing the scientific and technical quality of a research project plan and assigned to do so for one or more ARS research project plans. Peer reviewers may be an ARS scientist or non-ARS scientist.

Peer Review Recommendation

A document submitted by a peer review panel that contains a critical review of an ARS research project plan. Recommendations contain input from all members, but do not necessarily reflect a consensus of recommendations.

Primary National Program

The National Program in which a CRIS project is focused. ARS allows a research project to be coded to no more than two National Programs. The primary National Program must be assigned as either 60, 70, 80, or 100%. The corresponding secondary National Program would be assigned as 40, 30, or 20%. Nevertheless, projects may be related to other National Programs and so described by the National Program Staff in their National Program Overview.

Primary Reviewer

A peer reviewer assigned to perform a comprehensive and extensive review of a particular research project plan based upon applicable scientific or subject matter expertise. A primary reviewer is responsible for reading and assessing the project plan in-depth, documenting detailed recommendation for improvement if warranted, and when applicable, leading panel discussions about the project plan.

Secondary National Program

See definition of "Primary National Program."

Secondary Reviewer

A peer reviewer assigned to perform a comprehensive and extensive review of a particular research project plan based on applicable scientific or subject matter expertise. A secondary reviewer is responsible for reading and assessing the project plan thoroughly, documenting detailed recommendations for improvement if warranted, and participating actively in panel discussions about the project plan. The secondary reviewer reads and edits the final recommendations written by the primary reviewer. The secondary reviewer may act as the primary reviewer in his or her absence.

Scientist Year (SY)

The effort of a research scientist for one year. Fractional efforts in a given project are possible when a scientist is involved in more than one project during the course of a fiscal year. The term is also used in ARS as a synonym for a research scientist.

ACRONYMS & ABBREVIATIONS

ARS Agricultural Research Service

CRIS Current Research Information System

NPL National Program Leader NPS National Program Staff NPT National Program Team

OSQR Office of Scientific Quality Review, pronounced "Oscar."

SQR Officer Scientific Quality Review Officer

SY Scientist Year

6. Exhibits

Exhibit 1: Improving Research Through Peer Review; Roles of Peer Review

(Excerpt from the Agricultural Research Service Strategic Plan: Working Document 1997-2002. Page 36-38. USDA. April 1999.)

The deputy administrator, National Program Staff (NPS), is responsible for the systematic evaluation of National Programs and of progress towards achievement of the goals of the ARS Strategic Plan and the National Programs.

Review and evaluation of the National Programs and the research components, as well as locations, laboratories, management units, and research projects, serve to identify areas of significant progress, major limitations to further progress, emerging research problems and opportunities, and research that can be discontinued. That information will be used in setting priorities, planning and implementing redirections, developing budgets, and revising the ARS Strategic Plan, the National Programs, and the operational plans.

NPS is responsible for reviewing National Programs and for evaluating their progress and consistency with the ARS Strategic Plan and the Government Performance and Results Act (GPRA). To successfully carry out that responsibility, members of NPS will be recognized experts in their field and will be expected to maintain their knowledge of the latest scientific aspects of their assigned areas of responsibility. NPS members will also need broad experience and understanding of interdisciplinary research to recognize and exploit opportunities in related fields or to function as coordinators of problem-solving interdisciplinary teams. They will be prepared to provide authoritative advice as required. NPS members, then, serve the agency as guardians of the continuing relevance and correctness of the technical directions of the ARS National Programs.

NPS, Area, and center directors will manage the review and evaluation process, with NPS taking the lead on National Programs and Area Directors or center directors taking the lead on reviews of location, laboratories, or specific management units. Review and evaluation teams will include knowledgeable but impartial customers, stakeholders, and partners of ARS, selected from those who have no direct or personal stake in the outcomes of the specific reviews. Review and evaluation teams will develop a formal list of findings and recommendations and transmit them to the Area Directors and NPS. NPS and the Area Directors will then document and forward to the Deputy Administrator the plans for and actions taken to implement the recommendations of the review and evaluation team, or the reasons why specific recommendations cannot be adopted.

The purpose of the National Program evaluation is to keep Program problems, objectives, and outcomes relevant; keep Programs and staff responsive, gather information that will satisfy GPRA requirements; ensure the quality of science at ARS; and express ARS, mission. There are three components to the National Program evaluation process:

• Program performance evaluations—undertaken on an annual basis using a World

- Wide Web form. Objectives/outcomes will relate to GPRA reporting requirements, past performance and planned performance; standards for individual lab reviews; and a National Program review documents, to be released once in 5 years.
- Customer feedback surveys—undertaken every 5 years using a World Wide Web survey form. Objectives/outcomes will relate to GPRA reporting requirements, past performance and planned performance; for dissemination at the National Program reviews; and for customer acceptance.
- National Program review—undertaken every 5 years at a national workshop. Objectives/outcomes are expected to result in customers and stakeholders forging valuable and lasting relationships with ARS; an evaluation of the vision and rationale of each National Program, in context; an evaluation of the relevance of the research of each National Program; an evaluation of the effectiveness and responsiveness of ARS research; and an evaluation of the quality of the science.

National Program evaluation will not replace location, center, or other Program reviews and workshops conducted at the discretion of National Program Leaders and Area Directors.

Area and center directors will annually evaluate each research unit and laboratory under their supervision to monitor progress on operational plans and to ensure conformance with the ARS Strategic Plan and with the National Programs. Although technical matters may be considered in these annual evaluations, the main purpose will be to monitor operational capability and performance. The adequacy of available physical, financial, and human resources should be assessed in relation to the technical objectives to be achieved. Special attention should be given to opportunities for enhancing technical and leadership capabilities. Recommendations or actions arising from these evaluations will be formally communicated to the deputy administrator, NPS.

Scientific and technical excellence demands a continuing review and evaluation of progress by the scientists performing the work. Scientific decisions at the experimental level are best made by those scientists.

Exhibit 2: Review and Evaluation of National Programs

(Excerpt from "Improving Research Through Peer Review: A Report of the National Research Council" Page 3-5. National Academy Press. 1987.)

Peer review of science is the evaluation of the conceptual and technical soundness of research by those qualified to judge it by their status in the same or closely related research fields. Scientific peer review originated in the evaluation and approval of manuscripts before their publication (Garfield, 1986; Zuckerman and Merton, 1971). The practice of reviewing manuscripts was instituted to preserve the credibility of scientists and their institutions and ensure the quality of published literature.

Peer review was subsequently adopted to assess grant proposals, scientific Programs, and scientists. This evaluative mechanism is based on the premise that scientific peers, by virtue of their knowledge and experience, are best able to critically examine proposed or completed research projects and give scientific opinions concerning the projects' merit, significance, and feasibility.

Federal granting agencies that make extramural awards closely couple peer review of research proposals to allocation of research funds. These agencies include the National Science Foundation (NSF), the National Institutes of Health (NIH), and the USDA Competitive Research Grants Office. The exact mechanics of the review and decision-making processes vary somewhat in these and other such agencies, but their intent is the same—to allocate resources fairly in support of high-quality science in relevant fields.

These granting systems are competitive. Peer reviewers judge the scientific merit of proposed research projects and usually consider additional factors such as the scientist's past performance and the personnel and resources available to the laboratory. Reviewers generally assign an action class indicative of their assessment of the proposal relative to competing proposals. Agency Program directors use the reviews to judge whether or not the proposal merits the agency's support.

Peer review in granting agencies is largely prospective. That is, proposed research projects are prejudged on their likely scientific and technical merit, importance, and success. Reviewers do consider retrospective aspects, however, such as the quality and quantity of the investigator's previous scientific output. In contrast, other peer review systems are primarily retrospective. Such systems include personnel evaluations for promotion and tenure.

Considerations other than scientific excellence may enter into review processes. Such processes are collectively called merit review to indicate that other factors carry some weight. These factors may include nontechnical policy considerations. One consideration may be the utility and relevance of research to a goal extrinsic to the research project itself, such as new or improved technology development or the solution of social problems.

Another may be the impact on the infrastructure of science such as the relevance to mission-oriented goals of a sponsor, research site selection, or interdisciplinary character of some areas of science (NSF, 1986).

The role of peer review is most predominant is assessing research proposals from single principal investigators. These projects are known as "small science." In contrast, large. Complex, expensive, "big science" projects, such as the National Center for Atmospheric Research or the Fermi Accelerator, must pass the hurdles of technical scrutiny (peer review) and societal considerations (merit review). Most ARS research projects are conducted by single principal investigators managing small research teams, which is also common in universities. In this context ARS carries out small science. Therefore, technical peer review is sufficient for ARS projects. Before it appropriates funds, Congress has already considered the societal aspects of ARS scientific research.

Evaluative Role of Peer Review Within ARS

(excerpt)

Project peer reviews do not directly influence whether or at what levels ARS research projects are funded. The National Program Staff's stated goal for the ARS project peer review system is to improve the quality of research already requested and funded by the federal government. The noncompetitive funding process of ARS laboratories differs from that of many university laboratories, which must obtain the majority of their research funds from competitive, peer reviewed government granting programs. In addition. ARS science is mission-oriented and conducted mainly by tenured government scientists. Nevertheless, project peer review is quite applicable to the continuum of basic, developmental, and applied research that the ARS conducts.

Exhibit 3: Sample Peer Review Form

Project Title:	CRIS Number:
Lead Scientist:	Name of the Review Session:
Date:	Reviewer ID Number:

AD HOC REVIEW OF ARS RESEARCH PROJECT PLAN

The purpose of this review is to judge the technical merit of the planned research and to make constructive comments for improvement. The principle focus of this research has been determined by ARS to be essential to its mission, and funding has been approved at the planned level. Please provide both qualitative ratings and comments on each review criteria. Please list and number each significant recommendation being made. Be sure to briefly state the rationale or basis for suggestions made or questions raised. Each recommendation can include specific questions you believe should be addressed by the lead scientist. Please select an action class at the end of this form to indicate the level of revision you believe the subject project requires.

1. Merit and Significance: Are the project objectives relevant to the stated research goals and directions of the corresponding National Program? Will the successful completion of the project enhance knowledge of a scientifically important problem? Will the project lead to the development of new knowledge and technology? Are you aware of any other data/studies relevant to this research effort? If applied research, comment on the value of the research to its customers.

Project Title:	CRIS Number:
Lead Scientist:	Name of the Review Session:
Date:	Reviewer ID Number:

2. Adequacy of Approach and Procedures: Are the hypotheses and/or plan of work well conceived? Are the experiments, analytical methods, and approaches and procedures appropriate and sufficient to accomplish the objectives? How could the approach or research procedures be improved?

Project Title:	CRIS Number:
Lead Scientist:	Name of the Review Session:
Date:	Reviewer ID Number:

3. Probability of Successfully Accomplishing the Project's Objectives: What is the probability of success in light of the investigator or project team's training, research experience, preliminary data, if available, and past accomplishments? Are the objectives both feasible and realistic within the stated timeframe and with the resources proposed? Do the investigators have an adequate knowledge of the literature as it relates to the proposed research?

Project Title:	CRIS Number:
Lead Scientist:	Name of the Review Session:
Date:	Reviewer ID Number:
Additional Comments or Suggestion	is:
Action Class Judgement No Revision Required Minor Revision Required Moderate Revision Required Major Revision Required	No Revision Required – Needs no revision, but minor revision might be made. Minor Revision Required – Needs minor revisions, but objectives fit the National Program Action Plan; approaches to all objectives are sound. Project is Feasible. Moderate Revision Required – Moderate revision of an objective and/or one approach is needed. Project is feasible.
Not Feasible	Major Revision Required – Project should be sound and feasible after major revision. Not Feasible – Project is not feasible because of deficiencies in expertise and/or facilities, or has other major flaws that require a complete redesign and rewrite.

Exhibit 4: Sample Peer Review Recommendations and ARS Response

Project Title: Development of Gentle Intervention Processes to Enhance the Safety of Heat Sensitive Foods

Lead Scientist: Dr. John Doe National Program: 108 Food Safety-Postharvest

Reviewer Number: NNCK1120

- 2. Adequacy of Approach and Procedures: Are the hypotheses and/or plan of work well conceived? Are the experiments, analytical methods, and approaches and procedures appropriate and sufficient to accomplish the objectives? How could the approach or research procedures be improved?
- 1. The hypothesis that... condensing steam will inactivate bacteria on the surface of solid foods without causing thermal damage if the interfering air and water layers on the surface are removed by vacuum and the condensed steam is removed to evaporatively cool the surface... is scientifically sound and workable. Indeed, the group has developed and tested the technology with a pilot plant prototype and chicken pieces, which indicated a 2 log reduction of LM in initial studies. Further refinement will involve retrofitting the prototype to treat the whole carcass (surface, visceral cavity) and development of a field VSV pasteurization system. Additional studies will focus on ready-to-eat meats, specifically hot dogs (and the known LM hazard) and catfish, with both aspects under appropriate CRADAs. The former is a high priority research need for food safety regulatory agencies, and the contingency inactivation studies "in-package" (within plastic) should probably be elevated to practice in the proposal. The portion of the proposal indicating the development of models and process simulations, towards determining the mechanism of VSV inactivation, is appropriate, but of lower priority in the overall project schema. Any modeling aspect should be focused on process delivery and eventual development and validation of performance standards to support food safety.
- 2. The controversial theory that "pasteurization" of heat-sensitive foods is accomplished by applied voltage or magnetic field and, perhaps, can be demonstrated with the incumbents' "uniquely modified RF heater" is the overall working hypothesis for this objective. This entire objective is very high risk, but the payoff is potentially high. The proposal articulates a clear, stepwise protocol. The modified RF "heater" appears to be designed to offset the often-stated criticism towards the non-thermal theories that precise measurements of the time-"temperature" history and its spatial variations are lacking.

Recommendations:

1. Objective 1 - The proposal needs to incorporate a more specific explanation of the steps needed to determine the effectiveness of the VSV treatment. Will naturally occurring pathogen populations be known or established?

ARS Response: We added more detail to the plan or work. Specifically, we will use Null hypothesis to determine statistically significant differences between the treated and control, within 1 day, across 3 days, over weeks and seasons. Each company will have their own specific tests to run to determine effectiveness.

We will test for *Campylobacter* and generic *E. coli* at Athens. One company has expressed an interest in looking at *Salmonella*. At that plant, they will test for it. It is the objective to develop the process for commercial adoption. We expect individual companies will do more specific tests and share the data. In all cases in which it is feasible, we will try to establish the pathogens present.

2. Objective 1 – Although the primary focus of the research may be on reducing microbial populations on the surface of solid foods, the evaluation of the process should incorporate measurements of the process impact on product quality; color, texture, etc.

ARS Response¹: We agree, but that is best left to the companies to do. They are the 'product specialists' and are much better equipped to do those studies. They have the equipment, experience and personnel to do them. We added text to indicate that industry will do these tests as part of our collaborative arrangements.

The research on this objective is at the developmental stage. We need industry to cooperate in testing at processing plants. We will supply the equipment and expertise on the VSV intervention processor. We will do the microbiology evaluation although industry will undoubtedly do their own microbiology evaluation as well. Industry is best equipped to evaluate the consumer acceptance of the product. We are in a better position to do basic research into the mechanism and model the process.

3. Objective 1 – The portion of the proposal on models and simulation of the bacterial "destruction" process needs to be developed with much more specific information on the approach to be used and the outcomes to be achieved. The models should focus on process delivery and eventual development and validation of performance standards to support food safety.

ARS Response: We agree. This research objective belongs to a high level vacancy, as yet unfilled. However, we added a detailed research plan based on our conception. It is a difficult research assignment and we hope to hire a highly qualified engineer to do it.

4. Objective 2 – The hypothesis of the research should be reversed to prove that a non-thermal influence on inactivation of microbial cells does exist.

ARS Response: We concur and changed the order as suggested.

5. Objective 2 - The portion of the research on the non-thermal influence of electromagnetic energy on microbial inactivation will require a more detailed experimental design than presented in the proposal. Since the influence can be expected to be small, and a well designed statistical study is needed.

ARS Response: We expanded the text to give the details of the planned experiments. We are performing an engineering study to develop a process based on a nonthermal effect. The first step is to prove such an effect exists and is significant. If it is small it might be of scientific interest but is unlikely to form the basis of a new process. The effect must be large enough to justify developing a process. Therefore, we will look for a non-thermal effect within the framework of a steady state process.

6. Objective 2 - A portion of the research has a focus on mechanisms for inactivation of microbial cells due to electromagnetic energy. These investigations should be expanded to include all forms of electrical energy.

¹While it is appropriate for companies to conduct such evaluations for company products, research under ARS National Program 306 (Quality and Utilization of Agricultural Products) will address precommercial evaluation of new food safety interventions on product quality. An objective under Problem Area 1c., 'Factors and Processes that Affect Quality', of the NP 306 Action Plan, is to 'Evaluate effects of safety and environmental protocols on quality of foods.' This activity was sanctioned by NP 306 stakeholders in workshops and fits the mission and objectives for NP 306.

ARS Response: This phase of the research is meant to support the process development through a better understanding of the basic principles involved. There are insufficient funds to look at all forms of electrical energy. We must be selective and choose to investigate the form we consider has the greatest potential for commercialization.

Exhibit 5: Contents of the Panel Chair's Statement

Letterhead:

Date

Steven Huber, Scientific Quality Review Officer Office of Scientific Quality Review Agricultural Research Service, USDA 5601 Sunnyside Avenue, MS 5142 Beltsville, MD 20705

[Body: please answer these types of questions:

- 1. Did the [state the name of the panel] panel have discussions that reflected: -sound and credible scientific peer review
 - ideas, creative thinking, and alternative approaches to improve the quality of research that may not have been considered by Agency scientists and staff.
- 2. What were the most notable (positive or negative) characteristics of the discussion process and why:
 - -level of preparation for the discussion
 - -time spent discussing each project
 - -logistical arrangements
 - -exclusion of peer reviewers who had a conflict with the project
 - -understanding of the review criteria and roles as peer reviewers
 - -scoring and critique writing procedures
- 3. What suggestions do you have to improve the peer review process?
- 4. Overall, was this an effective peer review panel?

[Please note that, while your statement is directed to the Officer, it will be read by ARS Area Directors, National Program Staff managers, and other managers in the agency. Your statement will be held as part of OSQR's public records. Please do not list the names of the reviewers in your statement.]

[your signature & title]

Exhibit 6: Action Class Matrix

The following matrix is provided to give reviewers some guidelines for assigning appropriate action classes to project plans. Many projects plans will fit different action classes for different review criteria. In these cases, the reviewer must decide whether strengths or weaknesses in a particular criterion override those of other criteria. For example, a Project Plan could be rated "not feasible" because of a lack of appropriate personnel and/or facilities, but still be excellent in every other way.

Action Class	CRITERIA			Recommend:
	Merit and Significance	Approach and Procedures	Probability of Success	
No Revision Required	Objectives are important to the national interest and closely fit the national program action plan.	The objectives and Experimental Plan are well conceived and the project plan is clearly articulated.	necessary training and	No revision is required, but minor changes to the project plan may be made.
	The project will lead to new knowledge and technology, or will produce results of value to customers.	The objectives directly address the stated research goals.	The objectives are reasonable with resources available, and necessary equipment and facilities are in place.	
	Similar research is not being conducted elsewhere.	The procedures and analytical methods are appropriate and sufficient to accomplish the objectives.	The research team is completely aware of the relevant current literature in the area.	

Minor Revision Required	Objectives are important to the national interest and closely fit the national program action plan.	The Experimental Plan is generally well conceived and all of the objectives are sound. The project plan is basically feasible.	The research team has the training and experience to accomplish the stated goals.	The project plan is basically feasible as written but requires some revision to increase quality to a higher level.
	The project will lead to new knowledge and technology, or will produce results of value to customers.	The objectives address the stated research goals.	The objectives are generally reasonable with resources available, and essential equipment and facilities are available.	
	Similar research is not being conducted elsewhere.	Some minor changes to one or more objectives are suggested, and may involve modifications or alterations to specified procedures or analytical methods.	The research team is aware of current literature in the area.	

Moderate Revision Required	Revision	Objectives are important to the national interest and fit the national program action plan.	The objectives and experimental plan are generally sound, but perhaps not clearly articulated.	The research team has most of the training and experience necessary but some areas could be strengthened. One or more of the objectives needs some modification in order to be reasonable with resources available.	The project plan is basically feasible as written but requires moderate revision to one or more objectives, perhaps involving changes to the experimental approaches, in order to increase quality to a higher level. The project plan may also need some
	The project has potential to lead to new knowledge and technology, or to produce results of value to customers.	The objectives may need some modification to better fit the stated goals.	Most of the necessary equipment and essential facilities are in place but some aspects could be strengthened.	rewriting for greater clarity.	
		Similar research may be conducted at other locations suggesting some modification to the present project plan.	Moderate revision to one or more objectives may be required, and may involve changes in experimental approaches or analytical methods.	The research team is aware of most of the current literature in the area.	

Major Revision Required	One or more of the objectives may not closely fit the national program action plan. The project plan as written is not likely to lead to new	objectives may not directly address the stated goals. Major revision to one or more objectives may be necessary because of inappropriate hypotheses or in a dequate experimental approaches.	The research team may lack some important aspects of training or expertise. Several objectives are not in line with the resources	Substantial revision to one or more objectives is necessary, but the project plan should be sound and feasible after significant revision.
	knowledge or new n technology.		available.	
			Critical equipment, facilities or experimental tools are not yet in place or available to the research team.	
	Similar research is being conducted at other locations such that undesirable duplication of effort is apparent.		The research team is not aware of significant current literature in the area.	
Not Feasible	One or more of the objectives may not fit the national program action plan.	One or more of the objectives have major flaws, that may involve inappropriate hypotheses or completely inadequate experimental approaches.	The research team has substantive deficiencies in essential expertise or required facilities.	The project plan has major flaws or deficiencies, and cannot be simply revised to produce a sound project. If the project is not terminated, a complete redesign and rewrite are
	As written, the project plan will not lead to new knowledge or technology.	The objectives are unrelated to the stated goals.	The research team is completely unaware of current activity and literature in the area.	required.

EXHIBIT 7: Action Class Judgment Worksheet

EXTIDIT 7. AUGUST OIGGO	oaagiiioiit t	VOITOR	•		
United States Department of Agriculture Agricultural Research Service Office of Scientific Quality Review		Project Plan Title:			
National Program:		Lead Scientist	:		
Panel Dates:					
ACTIO	ON CLASS RA	TING WOR	KSHEET		
See Guidelines for Reviewing ARS Research Project Plans	Scientific Quality Review Officers: The Officer whose signature appears below agrees to treat the contents of this Plan as confidential and that no basis for a conflict of interest has been found. Final determination of conflicts of interest, which are outlined in the Guidelines for Reviewing ARS Research Project Plans, resides with the OSQR.				
Individual quality ratings translate into the following numerical values:	Reviewer #	Quali	ty Rating	Numeric	al Value
No Revision Required = 8 points No revision is required, but minor changes to the project	1				
plan may be made.	2				
Minor Revision Required = 6 points The project plan is basically feasible as written but	3				
requires some revision to increase quality to a higher level.	4				
Moderate Revision Required = 4 points The project plan is basically feasible as written but	5				
requires moderate revision to one or more objectives, perhaps involving changes to the experimental approaches, in order to increase quality to a higher level.	6				
The project plan may also need some rewriting for greater clarity.	7				
<u>Major Revision Required</u> = 2 points Substantial revision to one or more objectives is	8				
necessary, but the project plan should be sound and feasible after significant revision.	9				
Not Feasible = 0 points The project plan has major flaws or deficiencies, and	10				
cannot be simply revised to produce a sound project. If the project is not terminated, a complete redesign and	11				
rewrite are required.	12				
Per project plan, individual panelist quality ratings will be tallied, divided by the total number of panelists (panel members, plus panel chair, excluding	13				
ad-hoc reviewers), and rounded to the nearest tenth to arrive at a final project score. Final Project Ratings	TOTAL # Reviewers:		Total Rating:		
are as follows:	Average Rating:				
No Revision Required: >7.0 Minor Revision Required: 5.1 to 6.9 Moderate Revision Required: 3.1 to 5.0 Major Revision Required: 1.1 to 3.0 Not Feasible: <1.1	Scientific Quality Review Officer's Name			EVALUATION	
	(Please type or print name)			No Revision Required Minor Revision Required Moderate Revision Required Major Revision Required Not Feasible	
	Signature Date				

Exhibit 8: The ARS Research Project Plan Instructions and Format

Please use the electronic template provided on the OSQR Website at www.OSQR.ars.usda.gov in WordPerfect or MS Word and submit electronically through supervisory channels to the Office of Scientific Quality Review (OSQR). Please name the file: "[lead SY's name]projectplan" for plans created prior to peer review. Name the file: "[lead SY's name]revisedprojectplan" for plans created after peer review. If a lead scientist has more than one project in a review session, include unique digits from the CRIS number in the naming pattern.

The Plan should be formatted as follows: 8.5x11" letter portrait, single spaced, 1" margins all around 11-pt Arial or Helvetica font, full justified, no end-of-line hyphens

Header on all pages with **lead scientist's** name at the left and page numbers placed flush right, excluding the cover page. Footer on all pages with version date at the left.

For tables, omit all vertical lines; place single horizontal lines under the title, under the column headings, and at the bottom of the table, just above any footnotes. Do not enclose tables with lines or other borders. Avoid creating color graphics, unless necessary to thoroughly describe your plan or demonstrate scientific analyses. If color graphics are included and considered necessary, a note must accompany the plan stating that it must be printed in color. Compress files that exceed 1 megabyte. Avoid creating attachments to project plan files.

The Plan should not exceed 15 pages (20 pages if 2.0 SY or more) from **Objectives** through **Milestones and Expected Outcomes**. Up to two pages of schemes, figures and diagrams can be included in the text and will not be counted against the page limit. This first part should flow from one section to the next without new page breaks.

The Cover Page, Project Summary, Objectives, Literature Cited, Past Accomplishments of Each Investigator, Health, Safety, and Other Issues of Concern Statement, and Appendices should all be started on new pages. Suggestions, based on Project Plant Review Panel feed back is provided. (See the "©".) We think your project plan will be significantly improved if you consider each of the points marked by this symbol. This information was gleaned from extensive feedback from several panels.

Cover Page

Name of the Review Session—The name of the review session can be found in the initial direction (memo from the National Program Leader) you receive to start working on your prospectus. It identifies the national program and whether it is a panel or ad hoc review.

National Program – The title of and the percent coded to the National Program(s) under which the research described below is conducted.

Dates – State the general period in which the research project will be peer reviewed. (Visit the OSQR Website for scheduling information.)

Old CRIS Project Number – The CRIS number for the expiring project. If new, leave blank. If projects are being combined, list those that are being combined. If a project is being split, note that the old CRIS Project is being split during this process.

Management Research Unit – The six digit number including name of Management Research Unit (Example: 0000-00–Name of Management Research Unit)

Location – City and State.

Title – A brief, clear, specific description of the project. Used alone, it should provide a clear indication of what the project is specifically about. It should not contain more that 100 characters including letter, symbols and spaces. *Investigator(s)* – List all SY personnel (including vacancies) and percent commitment (SYs) to the project. Identify the lead scientist. If the research team includes scientists not employed by ARS, (e.g., this is an extramural project.) list them also but identify their employer.

Scientific Staff Years – List as a decimal, i.e., 2.75. (Does not include scientists not employed by the ARS.)

Planned Duration – List in terms of total months, i.e., 60 months. (See the OSQR website for more scheduling information.)

Signatures – Submit coverpages with the approving official's name typed in. 1)lead scientist and/or the research leader; 2)lab, institute, or center director; 3) the National Program Leader, 4) Area Director. (If line #2 is not applicable, please state "not applicable.")

Area Office: OSQR only accepts project plans that demonstrate the four approvals. Submit completely approved plans, in an electronic and hardcopy format, before and after (the final project if there is no re-review) peer review. Attach an original copy of an approval record, signed by the Area Director, to the hardcopy of the final project plan.

Project Summary - The objectives and research approaches of the Project Plan should be summarized in 250 words or less on the second page. The first two pages of the Project Plan are not counted against the page limit.

Objectives – A clear statement must be given of the specific objectives of the project that are attainable within the project time period (not to exceed 5 years) and with the physical resources committed to the project as discussed in the Approach and Research Procedures section. The statement should be complete enough to be used as the basis for scientific review. Elaborate, in paragraph form, the bullet statements from the Prospectus.

- © Panels have found that some projects are overly ambitious, in that they encompass an overly generous portion of the National Program Action Plan. Feasibility becomes questionable if the project appears to be significantly more than the assigned personnel and collaborators can do in five years.
- Panels also seem to have more problems with project plans that have apparently unrelated objectives. Some explanation of the rationale for how objectives relate or why they are contained in a single project might help.

Need for Research – A statement that provides information necessary for the review of the project based on its relevance to ARS National Program Action Plans. Use subsections to denote the following, which must be covered:

- Description of the problem to be solved.
- Relevance to ARS National Program Action Plan.
- Potential benefits expected from attaining objectives.
- Anticipated products of the research.
- Customers of the research and their involvement.
- Optional Congressional mandates related to the project.

© In general, panels have found too much emphasis on the Need for Research section and not enough on the Approach and Research Procedures section. The panels know that if your project falls within the National Program Action Plan, it is well justified. So, there is no need for page after page of justification, leaving little room for details in the Approaches and Procedures section.

Scientific Background – Do not repeat information provided in the Need for Research section. Discuss scientific literature and current technology as related to stated objectives and scientific feasibility of the project. This focused review should demonstrate that the investigator(s) know(s) and understand(s) the field of study. Relevant past projects of the investigator(s) of the proposed project should be discussed in terms of related objectives and to what degree they were met. A CSREES-CRIS search of research that is currently underway on the proposed project topic is required in this section.

- In the Scientific Background section, the proposed research should be clearly
 differentiated and/or related to research both inside and outside of ARS that has the same
 or similar objectives.
- © Preliminary data are very helpful to the panel as they evaluate the project plan. But, if preliminary data are mentioned, they should be shown. This information can go in the Scientific Background part of the Project Plan or in the Approach and Procedures section.

Remember, up to two pages of figures, schemes, and tables will not be counted as part of the 15 or 20 page limit.

Approach and Research Procedures – Use four subsections under this heading to elaborate on the following:

Lack of necessary detail in the Approaches and Procedures section has been the most

common criticism of Project Plans. Where appropriate, the scientists should tell why they are using a particular procedure rather than an alternative.

- © The Approach and Procedures section should tell who is going to do what and when they are going to do it. In other words, clearly identify the staff responsible for carrying out each key portion of the project.
- ©If you think there might be a question about whether an investigator has the capability of conducting a procedure (e.g., lack of publications in the area), if possible, more information should be provided to give the panelists more confidence in the investigator's chances of success.

Experimental Design – Describe in detail the scientific and experimental approach that is to be used and the research procedures that will be followed to attain objectives. This section should discuss, if applicable, what hypotheses will be tested; how they will be tested; and how experimental results will be evaluated.

Contingencies – Discuss approaches and experimental options that will be considered if the initial research plan is unsuccessful in evaluating hypotheses or attaining objectives.

© Carefully consider contingencies. The panelists realize that most of these projects will evolve during their five-year duration. You should make it clear that you have considered contingencies, depending on whether or not the primary plans and procedures are successful.

Collaborations – Describe collaborations with scientists outside of this project (ARS and external to ARS) that are necessary to attaining the objectives. Necessary is meant to mean required for a successful project outcome. Necessary collaborations should be documented by an appended electronic letter from the scientist briefly detailing the collaboration. The letters of intent to collaborate must discuss what the collaborator will do and what level of commitment is anticipated.

© If a collaboration is documented, the collaborator must give more information than an agreement to collaborate. The collaborator should tell what they intend to do and how much of their time they intend to spend in the collaboration. Vague letters of collaboration are not useful to the panel review process and have been a sore point with the panels.

If appropriate, sets of the above subsections may be used for each major objective.

Physical and Human Resources – Describe availability of major physical resources (i.e., facilities, major instrumentation and equipment, etc.) that are necessary to accomplish the research. Estimate the number (FTE) of non-Cat. I project personnel (postdocs, technicians, students, etc.) who will be available for this project.

©Human and physical resources should be described. In many cases, the panels were left wondering if the scientists assigned to the projects had sufficient technical and scientific help. This includes numbers and training of technicians, students, postdoctoral scientists, and collaborators. If there is a Category I Scientist vacancy, there should be a description of the scientific background that you would like in the scientist to be hired and how that background will support the project. Describe any substantial physical resources that are necessary for the project (e.g., an electron microscope).

Milestones and Expected Outcomes – Describe a series of milestones (significant points in the project where progress can be documented) for the life of the project. Construct a time-line estimating when these milestones can be reasonably met, showing which scientists will be responsible for each milestone or step in the process. Describe how progress will be documented and evaluated (*i.e.*, products of the research).

<<AT THIS POINT, the Plan should be no more than 15 pages (20 pages if 2.0 or more SY). The plan can have up to two pages of illustrative material (e.g., schemes, figures, flow diagrams) that will not be counted against the page limit.>>>

Literature Cited – Begin the Literature Cited on a new page. Literature can be listed alphabetically by author or in order of citation in the text. If papers are cited by author(s) and year, they must be listed alphabetically in the Literature Cited section. However, any citation format accepted by a scientific journal that includes all authors, article title, and complete page numbers may be used. Only material or papers that are published or in press should be provided in this section. Theses and dissertations, state and federal documents intended for professional distribution, and peer-reviewed proceedings of meetings generally are acceptable citations. Meeting abstracts, unpublished materials, and non-peer-reviewed materials are not acceptable as citable materials.

Past Accomplishments of Investigator(s) – Begin each investigator's past accomplishments on a new page. In one single-spaced page or less per scientist, provide education and work experience, and describe accomplishments of the investigator(s) of this project over the past 10 years that are significant and pertinent to the proposed research. Follow each investigator's past accomplishments with a list of all peer-reviewed publications authored by the investigator in the past 5 years and all publications by the investigator that are clearly relevant to the area of this research project during the past 10 years.

© Use of figures, schemes, and tables can greatly enhance the plan, especially the milestones and expected outcomes section. Good examples of milestones table are seen by are can be found by visiting www.OSQR.ars.usda.gov. Remember, up to two pages of figures, schemes, and tables will not be counted as part of the 15 or 20 page limit.

Order the publications according to publication date, most recent last. Any citation format accepted by a scientific journal that includes all authors, complete article title, and complete page numbers may be used.

Health, Safety, and Other Issues of Concern Statement – *Visit* <u>www.OSQR.ars.usda.gov</u> for templates. – Address the safety concerns for seven issues including identification of necessary permits either in hand or requested. If not relevant, please state as such.

- Animal Care
- Endangered Species
- Environmental Impact Statement Scientists and their Research Leaders shall make a determination on the potential environmental impact of the research. Many ARS research projects are conducted in contained facilities such as laboratories, greenhouses, or field plots. Such projects would be considered to the Categorically Excluded under ARS National Environmental Policy Act regulations. Project statements would then include the following statement: "THE RESEARCH PROJECT HAS BEEN EXAMINED FOR POTENTIAL IMPACTS ON THE ENVIRONMENT AND HAS BEEN FOUND TO BE CATEGORICALLY EXCLUDED UNDER ARS REGULATIONS FOR THE NATIONAL ENVIRONMENTAL POLICY ACT." The appropriate NPL(s), in discussion with the scientist about a replacement project, will decide whether it is Categorically Excluded.
- Human Study Procedure
- Laboratory Hazards
- Occupational Safety & Health
- Recombinant DNA Procedures

Appendix – On a new page, list appendices by page number (if in the main file), or by filename (if additional files are submitted electronically). Following the list of appendices page, scan the collaborators letters into the project plan appendices or create one pdf file, that combines the letters with the rest of the document.

Compressed files are acceptable and preferred if the project plan exceeds 1 megabyte.

Exhibit 9: Peer Reviewer Guidelines

Conflict of Interest—Do not review any ARS project plan if you have an institutional or consulting affiliation with the submitting institution, investigators, or collaborators, or will gain some benefit from the project, financial or otherwise. Also, please decline the review if, during the **past four years**, any of the following relationships are applicable with respect to the submitting applicants and collaborators: collaboration on research projects; co-authorship; thesis or postdoctoral advisorship; work as graduate students or postdoctoral associate. If you are uncertain about potential conflicts, please contact the OSQR for advice on your decision.

Confidentiality—ARS project plans may include detailed information about the underlying research and existing and anticipated research results that is considered by ARS to be proprietary or confidential information. For this reason, do not copy, quote, or otherwise use material gained during the Peer Review Process. If you believe that a colleague can make a substantial contribution to the review, consult with the OSQR before disclosing any information. When you complete the review, destroy the project plan and all associated materials from the OSQR.

Mission²—Our primary interest is in your evaluation of the technical and scientific quality of the research proposed for solving the problem or answering the hypothesis that is being addressed. If you are critical of the approach taken in a project plan or skeptical of the feasibility of a project, we would like your recommendations for improvement. Please see the attached <u>"Example of a well written set of recommendations."</u>

Review Criteria—There are 3 categories of review criteria:

1) Merit and Significance. For this criterion, ARS is primarily interested in whether the problems to be solved or addressed fit within the National Program Action Plan to which the Project Plan is assigned. The National Program Action Plan has been developed with input from stakeholders, congressional mandates, customers, and ARS and non-ARS scientists. Other aspects of these criteria that should be addressed are:

Will the successful completion of the project enhance knowledge of a scientifically

_

Public Law 105-185, June 23, 1998. An Act To ensure that federally funded agricultural research, extension, and education address high-priority concerns with national or multistate significance, to reform, extend, and eliminate certain agricultural research programs, and for other purposes. Title I, Sec. 103(b) Advisory Board Review—On an annual basis, the Advisory Board shall review—(1) the relevance to the priorities established under Sec. 102(a) of the funding of all agricultural research, extension, or education activities conducted or funded by the Department; Sec. 103(d)(1) Peer Review Procedures—The Secretary shall establish procedures that ensure scientific peer review of all research activities conducted by the Department. Sec. 10 once every five years, that each research activity of the Department and research conducted under each research program of the Department has scientific merit and relevance. Sec. 104(d)(4) Composition of Review Panel—(A) In General—A review panel shall be composed of individuals with scientific expertise, a majority of whom are not employees of the agency whose research is being reviewed. Sec. 104(d)(4)(B) Scientists from Colleges and Universities—To the maximum extent practicable, the Secretary shall use scientists from colleges and universities to serve on the review panels. Sec. 104(d)(5) Submission of Results—The results of the panel reviews shall be submitted to the Advisory Board. 3(d)(2) Review Panel Required—As part of the procedures established under paragraph (1), a review panel shall verify, at least

important problem?

- Will the project lead to the development of new knowledge and technology?
- Are you aware of any other data/studies relevant to this research effort?
- If applied research, peer reviewers comment on the value of the research to its customers.
- 2) Adequacy of Approach and Procedures. This evaluation criterion measures the scientific quality of the proposed research. Questions to be answered are:
 - Are the hypotheses and/or plan of work well conceived?
 - Are the experiments, analytical methods, and approaches and procedures appropriate and sufficient to accomplish the objectives?
 - How could the approach or research procedures be improved?
 - 3) Probability of Successfully Accomplishing the Project's Objectives. The feasibility of the project is evaluated by this criterion. The panel will determine:
 - The probability of success in light of the investigator or project team's training, research experience, preliminary data if available, and past accomplishments;
 - Whether the objectives are both feasible and realistic within the stated timeframe and with the resources proposed; and
 - Whether the investigators have an adequate knowledge of the literature as it relates to the proposed research.

Satisfying each of these three criteria is essential to the implementation of research project plans.

Action Classes--After their discussion (panel reviewers) or completing the peer review form (ad hoc reviewers), each peer reviewer makes a judgement level of project modification needed to assure project quality. OSQR converts the action classification into a numerical score, averages the group of action classes submitted, and assigns a final action to the project plan.

- 1. No revision required. No revision is required, but minor changes to the project plan may be made.
- 2. Minor revision required. The project plan is basically feasible as written but requires some revision to increase quality to a higher level.
- 3. Moderate revision required. The project plan is basically feasible as written but requires moderate revision to one or more objectives, perhaps involving changes to the experimental approaches, in order to increase quality to a higher level. The project plan may also need some rewriting for greater clarity.
- 4. Major revision required. Substantial revision to one or more objectives is necessary, but the project plan should be sound and feasible after significant revision.
- 5. Not feasible. The project plan has major flaws or deficiencies, and cannot be simply revised to produce a sound project. If the project is not terminated, a complete redesign and rewrite are required.

Panel Discussions—Panel discussions are valuable to creating a single critique that reflects the most important, prominent points made by the reviewers. The primary reviewer is responsible for writing the recommendations and must use his or her best judgement in deciding on which points made in the discussion (also documented on the *Peer Review of ARS Research Project* forms) will be reported back to the researchers. No consensus of opinion is required.

Nature of ARS's Research Projects —Each project was created in response to a congressional mandate and/or to a workshop involving mostly non-ARS stakeholders. Input from these external groups is used to formulate National Program Action Plans for ARS's 22 national programs. You will review only those projects that are coded more than 50% to a particular national program.

ARS's Peer Review Process is dramatically different from an extramural competitive grants review. You'll review funded, intramural project plans. Some of the research is hypothesis driven. ARS projects usually contain long-term and/or high-risk research on national problems. These project plans cover the next five-years. Thus, we have asked the scientists to provide research contingencies when appropriate. Second, as mentioned above, some of the projects involve more than one national program. With a given project proposal assigned as a primary or secondary reviewer, you may not feel qualified to evaluate all of the project (e.g.,part of the project deals with another national program). If so, please let the Panel Chair or OSQR Officer know as soon as possible.

Documentation—Use the provided *Peer Review of ARS Research Project* forms for your comments. (The forms will accompany the project plans.)

Planning and Preparation—We strongly encourage you to read the National Program's Action Plan prior to reviewing the project plans. In most cases, the Action Plan will be available from the ARS Web Page or via e-mail. We anticipate that it will take a few hours to read, interpret, and comment on each project plan. You may be given an overview of the National Program to aid your understanding of how the program is designed. Panel reviewers are given approximately 1 hour to discuss their individual comments on each project plan.

The size of these projects vary considerably, with some being limited in scope and personnel while others are wide ranging with several objectives. Nevertheless, the length and format of the project plans are uniform in order to limit your workload. The key information in project plans is limited to 15 or 20 pages, depending on the number of scientists; which includes the objectives, a description of the need for the research, background, approach, milestones, and expected outcomes. However, you can expect the entire project plan to be an average of 40 pages; which includes bibliographies, information about the scientists, collaboration letters, and other material.

The Final Recommendations—Primary reviewers have the responsibility for preparing the final recommendations that summarize the key findings of the panel. Your Panel Chair will validate the recommendations before we except them

Debriefing—Panel reviewers will be asked to tell us about their experience as a peer reviewer. Your comments help to improve how we conduct peer review sessions. Your honesty and sincerity is appreciated.

Obtaining Other Information—If you have a question that is not answered by reading the project plan or other materials, please call the Office of Scientific Quality Review, (301) 504-3282. We will get the answer for you.

EXAMPLE OF A WELL WRITTEN SET OF RECOMMENDATIONS:

Project Title: Development of Gentle Intervention Processes to Enhance the Safety

of Heat Sensitive Foods

Lead Scientist: Dr. ARS Scientist **National Program:** Food Safety

Reviewer Number: AAAA1120

Adequacy of Approach and Procedures: Are the hypotheses and/or plan of work well conceived? Are the experiments, analytical methods, and approaches and procedures appropriate and sufficient to accomplish the objectives? How could the approach or research procedures be improved?

Comments:

- 1. The hypothesis that... condensing steam will inactivate bacteria on the surface of solid foods without causing thermal damage if the interfering air and water layers on the surface are removed by vacuum and the condensed steam is removed to evaporatively cool the surface... is scientifically sound and workable. Indeed, the group has developed and tested the technology with a pilot plant prototype and chicken pieces, which indicated a 2 log reduction of LM in initial studies. Further refinement will involve retrofitting the prototype to treat the whole carcass (surface, visceral cavity) and development of a field VSV pasteurization system. Additional studies will focus on ready-to-eat meats, specifically hot dogs (and the known LM hazard) and catfish, with both aspects under appropriate CRADAs. The former is a high priority research need for food safety regulatory agencies, and the contingency inactivation studies "inpackage" (within plastic) should probably be elevated to practice in the proposal. The portion of the proposal indicating the development of models and process simulations, towards determining the mechanism of VSV inactivation, is appropriate, but of lower priority in the overall project schema. Any modeling aspect should be focussed on process delivery and eventual development and validation of performance standards to support food safety.
- 2. The controversial theory that "pasteurization" of heat-sensitive foods is accomplished by applied voltage or magnetic field and, perhaps, can be demonstrated with the incumbents' "uniquely modified RF heater" is the overall working hypothesis for this objective. This entire objective is very high risk, but the payoff is potentially high. The proposal articulates a clear, stepwise protocol. The modified RF "heater" appears to be designed to offset the often-stated criticism towards the non-thermal theories that precise measurements of the time-"temperature" history and its spatial variations are lacking.

Recommendations:

- 1. Objective 1 The proposal needs to incorporate a more specific explanation of the steps needed to determine the effectiveness of the VSV treatment. Will naturally occurring pathogen populations be known or established?
- 2. Objective 1 Although the primary focus of the research may be on reducing microbial populations on the surface of solid foods, the evaluation of the process should incorporate measurements of the process impact on product quality; color, texture, etc.
- **3.** Objective 1 The portion of the proposal on models and simulation of the bacterial "destruction" process needs to be developed with much more specific information on the approach to be used and the outcomes to be achieved. The models should focus on process delivery and eventual development and validation of performance standards to support food safety.

Exhibit 10: The Panel Peer Review Process: Step by Step Guidelines

(See Flowchart on the last page.)

Preliminary Planning

4-8 weeks

- 1. OSQR gives the National Program Team (NPT) an orientation to discuss:
- projects found to be coded greater than 50% to the National Program,
- policies on adding, exempting, or postponing projects. Also discusses methods of grouping projects,
- schedule of key deadlines: starting the process, when prospectuses and project plans are due to OSQR, anticipated implementation date. Holidays and standard nonworking days are integrated,
- requirement for National Program direction memos and approvals,
- National Program Action Plan and optional National Program overview,
- discuss requirement for the NPT to make a presentation at the panel's orientation,
- suggestions for peer reviewers, (OSQR also clarifies the absence of direct involvement of ARS employees, other than those in OSQR, in the selection and activities of panel chairs and peer reviewers.)
- overview of the Peer Review Process.
- 2. National Program Team prepares a list of projects to be peer reviewed and another list of projects not being peer reviewed and the rationale for exempting or postponing them. The two lists are reviewed for concurrence by each appropriate Area Director and Associate Deputy Administrator.
- 3. Using the list of key dates provided by OSQR, the National Program Team begins coordinating deadlines with the Area offices for:
- reviewing working drafts of prospectuses (optional),
- final prospectuses,
- project plans and revised project plans
- 4. For each project being peer reviewed, the National Program Team prepares a direction memo containing information about:
- directions to begin the peer review process by writing a prospectus,
- requests for working drafts of the prospectuses,
- the project's objectives and relationship to the National Program Action Plan (optional),
- a form for suggesting peer reviewers,
- schedule and format instructions for writing prospectuses and project plans,
- list of projects in the review session.

Copies of the approved list and direction memos are given to OSQR prior to sending memos.

- 5. OSQR verifies that the format of the lists, schedule, prospectus directions, and project plan directions are consistent and up-to-date.
- 6. The National Program Team distributes their memos. Any changes to this initial list of projects, whether adding or removing projects, must be made through the appropriate Area Director's Office and copied to the appropriate National Program Staff and research unit. Address these requests to add, postpone, or exempt a project to the Peer Review Program Coordinator.
- 7. OSQR begins retaining panel chairs.
- 8. Area Offices work with their research units to prepare staff for completing the requirements of the peer review, including but not limited to:
- referencing this Manual, other related instructions, training materials, and websites. (i.e., such as the OSQR website--osqr.ars.usda.gov.)
- discussing roles and responsibilities of the research unit and other ARS offices in writing and approving peer review-related documents
- tracking and formatting of peer review-related documents.
- clarifying the project implementation process and overall requirements for intramural peer review and other reviews required by ARS.

Prospectus Development

8 weeks

- 1. Research leaders and lead scientists draft their 2-page prospectuses and conflicts of interests. If requested, lead scientists send working drafts to the National Program Team before beginning the approval process. Once complete, lead scientists gain comments and approval from their Center, Institute or Lab Director. The prospectuses are then sent to the appropriate Area Director.
- 2. Area Directors perform their review and approval and also direct the labs to set up a peer review approval record in Research Management Information System, for each project, using the project's new title and background information stated in their prospectuses. Area Directors send the prospectuses on to the National Program Team.
- 3. National Program Team performs their review and approval and then forward the fully approved prospectuses to OSQR. The National Program Team also distributes directions to begin preparing the project plans, and specifies deadlines.
- 4. OSQR gives Panel Chairs an orientation.

Project Plan Development

18 weeks

- 1. Research Leaders and lead scientists write their project plans and gain comments and approval from their Center, Institute or Lab Director. The project plan is then forwarded to the Area Director. The Area Director reviews and approves each project plan, as well as gains input and approval from the National Program Team.¹ The Area Office ensures that project plans are in the format requested by OSQR.
- 2. The Area forwards the fully approved project plan to OSQR in electronic and hardcopy format.
- 3. OSQR and panel chairs prepare peer reviewers for the peer review.

Peer Review

6 weeks

OSQR distributes project plans, National Program Overview (optional), and National Program Action Plan to peer reviewers.

Revision and Implementation

6-10 weeks, depending on the results of the review.

- 1. OSQR electronically sends Area Directors the results of the panel reviews for individual projects and copies the National Program Staff. The peer review results include:
- instructions to respond to each recommendation,
- the SQR Officer's comments on the review and possibly suggestions for handling projects that receive "major revision" and "not feasible" action classes,
- the primary reviewer's recommendations,
- the SQR Officer's Action Class Judgment Worksheet.
- 2. Steps to revision and implementation:
 - A. Lead scientists of projects that receive a "no revision," "minor revision," or "moderate revision," revise their project plans and document their response to the review as instructed by OSQR.
 - B. Lead scientists then gain comments and approval from their Center, Institute or Lab Director.
 - C. Project plans and their accompanying "ARS Response" files are then forwarded to the appropriate Area Director. Area Directors review and approve project plans and ARS Responses, as well as gain input and approval from the National Program Team. The Area Office ensures that project plans and "ARS Responses" are in the format requested by OSQR.

¹To ease lead scientists' analyses and revision duties, we recommend that Area Offices avoid simultaneous review and commenting with the National Program Teams. For greatest efficiency, Area Offices should coordinate review and approval routes early in the project plan process.

D. The Area Office forwards fully approved project plans and their accompanying ARS Responses to OSQR in electronic and hardcopy format. The project plan hardcopy formats contain original signed copies of a Record of Approval, headed by the title and CRIS number of the project, which states:

"The attached Plan for the project identified above was created by a team of credible researchers and internally reviewed and approved by the team's management and national program leader to establish the project's relevance and dedication to the Agricultural Research Service's mission and Congressional mandates. The Project Plan has completed a scientific merit peer review in accordance with the Research Title of the 1998 Farm Bill (PL105-185) and was deemed feasible for implementation. Reasonable consideration was given to each recommendation provided by the peer reviewers.

Having completed these actions, I submit to implementing this Project Plan."

"Records of Approval" must be signed and dated by the Area Director (or designee).

- E. The SQR Officer reviews the ARS Responses. If necessary, he/she sends the appropriate Area Directors suggestions to improve the ARS Response, and completes all certifications to close the Process.² OSQR sends the certification to Area Directors and copies the National Program Staff.
- F. Panel reviewers receive ARS's response to their recommendations.
- 3. Project plans that receive a "major revision" or "not feasible" action class require the appropriate Area Director's decision for how to proceed. (See the "Action Classes" section in the Manual.)
- 4. Lead scientists with project plans that need a re-review by the original panel complete steps in #2 above, however the "Record of Approval" is not signed until the project plan receives a more favorable peer review.
- 5. OSQR assigns projects plans that require a complete re-write to the next ad hoc review scheduled for that National Program.

²The Area Director should then notify the Research Leader/Lead Scientist to implement the project by submitting an AD-416/417 for approval by line management. After the Area Director's approval, the new AD-416/417 should be transmitted to the National Program Staff (NPS) through RMIS. The lead National Program Leader will review the coding and instruct the NPS Program Analyst, to make any corrections or additions to the coding submitted.

ARS Peer Review Process OSQR Timeline NPS Area Director Center/Institute/ **Research Leader Preliminary Planning** Lab Director Orients NP Teams **Develops** 4-8 weeks Reviews, concurs Acknowledge directions and forward Sends complete peer review prospectuses with on procedures, key and forwards deadlines, and direction to Area Directors. lead scientist peer review directions formats. Send working draft to NP Team if requested. **Review & Comment** Submits prospectus Development 8 weeks for approval. **Prospectus** Each manager reviews and approves prospectuses and forwards them on to the next office. Selects reviewers Sends instructions to Area Acknowledge Prepares project Reviews, concurs Directors on preparing project directions and forward Project Plan Development 18 weeks plans with lead and forwards peer plans scientist. review directions Submits project Area Directors review and approve project plans and solicit Reviews and approves plans for comments and approval from the NP Team. Sends final approval. approved project plan to OSOR. Review 6 weeks Obtains panel or ad hoc peer Peer review of the project plans Acknowledges Reviews, concurs Forwards Panel cc NPS Responds to peer review recommendations and forwards Report to Area **Response and Revision** and forwards comments and makes peer review directions Directors appropriate revisions with lead scientist. 6 weeks OSQR certifies the process and the ARS Area Directors review and approve revised project plans & response. Returns ARS response. Solicits comments and approval from the NP Reviews and approves certification to Area Team. Sends final approved project plan to OSOR. Directors; copies NPS Submits revised project to begin the plans for approval. implementation process. Submission of potential peer reviewers to OSQR – anytime. 4 wks additional time for projects to be re-reviewed.